Recommendations for the Presidential Transition Team

The following documents are being submitted on behalf of and with input from national, state and local organizations representing persons infected and affected by HIV/AIDS, including minority communities, gay men, women, HIV medical providers, HIV housing providers, AIDS service organizations, state AIDS programs, and AIDS legal advocates.

We welcome the incoming administration and are encouraged by President Elect-Obama's strong statements in support of working to end the HIV/AIDS epidemic in the United States including the creation of a National AIDS Strategy.

The following pages outline very specific actions that the new Administration can take to address the domestic HIV epidemic. Much of the work in this document has taken place in coalition with organizations from AIDS in America, the Federal AIDS Policy Partnership, and others who have worked in support of the National AIDS Strategy. We particularly wish to thank members of the various Federal AIDS Policy Partnership Work Groups who were involved in creating the Section 1 specific recommendations. A tremendous amount of work on this document took place in a short period of time and we are appreciative.

Finally, we are pleased to offer our assistance to President-Elect Obama and his advisors on the Presidential Transition Team as you work to improve the federal government's response to the domestic HIV/AIDS epidemic.

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The following binder represents the combined efforts of HIV/AIDS community leaders to offer recommendations for actions relating to the HIV/AIDS epidemic that can be taken by the next Administration. This binder contains two sections bringing together all known domestic HIV/AIDS policy transition documents along with short action recommendations suggesting specific actions that the new Administration may wish to take immediately or shortly after assuming office.

Section 1:

Section 1 of the binder presents short priority recommendations which are derived from the community transition documents (contained in Section 2). These recommendations do not require Congressional action but if implemented would ensure better delivery of services to those living with HIV/AIDS, enhance prevention efforts, and help reduce stigma and discrimination against those infected and affected by this deadly disease.

The Section 1 recommendations are arranged by department and agency. They are specific as to the issue being addressed, provide a short explanation about the issue, and give a requested action. Additionally, the requested action is further developed in a recommendation section and we provide the process by which the recommendation can be implemented. There may be an example letter or policy attached to the

recommendation. These recommendations are solely administrative or regulatory in nature and consequently can be accomplished by the Administration without Congressional action.

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Tab G – Department of Health and Human Services - Centers for Medicare & Medicaid Services – Medicaid

- *Issue:* Medicaid coverage for routine HIV testing and counseling
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Tab H – Department of Health and Human Services – Centers for Medicare and Medicaid Services – Medicare

- *Issue:* Allow Expenditures made by the AIDS Drug Assistance Programs to count towards True-out-of-Pocket costs under Medicare Part D
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Tab I – Department of Health and Human Services – Health Resource and Services Administration

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Tab L – Department of Justice – Bureau of Prisons

- *Issue:* The need to increase access by incarcerated persons to barrier protection devices, counseling, and prevention education to reduce transmission of HIV and other sexually transmitted infections (STI)
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Section 2:

Section 2 of the binder presents the domestic HIV/AIDS policy transition documents along with two cover transition memos. Most, if not all of these documents have previously been delivered to the transition team. Therefore most of the documents are not included in this initial electronic version. The recommendations in Section 1 are based on activities prioritized in Section 2. It is worth stating that a review of the transition documents will show that few, if any of the recommendations contradict each other. Thus the national and local organizations and people infected with and affected by HIV/AIDS strongly urge the administration to maintain these transition documents as a guide for activity throughout the first term.

Tab A – Community Letter
Tab B – Transition Memo
Tab C – Framework for Developing an Effective National AIDS Strategy for the United States: October 2008
Tab D – AIDS in America: Recommendations for the First 100 Days of Office of the 44th President of the United States
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Tab F – National AIDS Strategy for Women in the United States: Submitted by the National Women and AIDS Collective - October 2008
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Tab H – The Stand Against AIDS - A Call from the Community for President Obama to Develop a National AIDS Strategy - November 2008
Tab I – The ADAP Coalition: Recommendations for the Next Administration and Congress
Tab J – Advancing Reproductive Rights and Health in a New Administration
Tab K – National Black Gay Men's Advocacy Coalition HIV/AIDS Policy Recommendations for the Administration of President-Elect Barack Obama
Tab L – Guiding Principles for LGBT Inclusion in Healthcare Reform

Note: For additional information on any of the issues in this document please contact Ronald Johnson, Deputy Executive Director at AIDS Action, 202-530-8030 ext. 3094 or rjohnson@aidsaction.org.

Section 1
Tab A

Executive Office of the President
Executive Orders

Executive Office of the President

Issue: **Initial Steps to Develop a National AIDS Strategy for the United States**

Explanation: The United States response to the domestic HIV/AIDS epidemic has had many important successes, including delivery of lifesaving treatments to thousands of people and use of evidence-based interventions to prevent hundreds of thousands of HIV infections. Yet the outcomes of the domestic response to AIDS remain unacceptable: infection rates have not fallen in at least eight years and there is a new HIV infection every ten minutes; half of people living with HIV/AIDS in America are not in care; and there are profound racial disparities in rates of HIV infection and survival after diagnosis with HIV disease. The federal government's domestic AIDS effort is in many ways a patchwork of uncoordinated and unaccountable programs lacking a comprehensive strategic plan driven by clearly defined goals. To address this shortfall in our domestic AIDS response, President-Elect Obama has committed to develop, "a comprehensive national HIV/AIDS strategy that includes all federal agencies. The strategy will be designed to reduce HIV infections, increase access to care and reduce HIV-related health disparities. His strategy will include measurable goals, timelines and accountability mechanisms."[1] Both the House and Senate have included $1.4 million in their FY09 Financial Services and General Government Appropriation bills for the White House budget for development and implementation of a National AIDS Strategy.

Requested Action: **1) Appoint White House-Level Director and Staff to Lead on the National AIDS Strategy, and, 2) Appoint National AIDS Strategy Panel**

Recommendation: The President should appoint staff, including a Director, to the White House Office of National AIDS Policy (ONAP) and charge them with leading development and implementation of a National AIDS Strategy. In addition, through ONAP and the Domestic Policy Council, the President should appoint a National AIDS Strategy Panel composed of experts on HIV/AIDS from every Department of the United States Government with responsibilities for responding to the epidemic, representatives of key non-governmental and civil society organizations, people living with and at risk for HIV, and other stakeholders to develop a National AIDS Strategy. This panel should hold at least one meeting at which it receives public input into the development of the Strategy, and at least two meetings at which its deliberations are open to the public. The Strategy it develops should not simply be a list of recommendations, but rather an operational roadmap for the federal government to achieve improved outcomes in the response to HIV/AIDS. The Strategy should be fully developed no later than January 20, 2010, and be operational until December 31, 2014.

Process by which the Recommendation can be implemented: Presidential appointment of Director, other staff and Panel.

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[1] http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids/

Executive Office of the President

***Issue:* Invigorate federal efforts to respond to the disproportionate impact of HIV/AIDS among African Americans**

Explanation: In 2007, the U.S. Centers for Disease Control and Prevention (CDC) rightly identified that while HIV/AIDS is a threat to the health and well-being of many communities in the United States, it is a major health crisis for African Americans. Local, state, and federal efforts to combat HIV among African Americans have been increased over time, and many African American leaders and organizations across the United States have committed themselves to reducing the impact of the disease in their communities. These efforts, nevertheless, have been unsuccessful at decreasing the persistently high rates of HIV infection among blacks.

CDC created a program called the "Heightened National Response to the HIV/AIDS Crisis Among African Americans (HNR)." According to CDC, the response is "one that ignites focused, collaborative action among public health partners and community leaders, is vital at this time to reduce the toll of HIV/AIDS on blacks. Such a heightened response must focus on 4 main areas: (1) expanding the reach of prevention services, (2) increasing opportunities for diagnosing and treating HIV, (3) developing new, effective prevention interventions, and (4) mobilizing broader community action."[2]

CDC is currently completing a rigorous review of the HNR that will inform changes to the initiative. The program has been inadequately funded to date, scarcely involved community stakeholders and other federal departments and agencies, and failed to adequately address the needs of at-risk subpopulations, such as gay/bisexual men, other men who have sex with men and heterosexual women.

***Requested Action:* For National Black HIV/AIDS Awareness Day, the President should issue an executive order requiring nine federal agencies (listed below) and their respective agencies to support CDC's Heightened National Response to the HIV/AIDS Crisis Among African Americans with specific and funded activities, policy development, and proclamations. In addition, the President should require from CDC a letter of clarification on the specific steps to achieve HNR's goals in response to new HIV incidence and prevalence estimates and vis-à-vis a new, coordinated approach with the Domestic Policy Council and the nine federal departments listed in the aforementioned Executive Order.**

Recommendation: No later than February 7, 2009, National Black HIV/AIDS Awareness Day, the President should issue an Executive Order to member of his Cabinet with authority over relevant federal departments, listed below, requesting a detailed internal review of activities their Departments will undertake to support the U.S. Centers for Disease Control and Prevention's Heightened National Response to the HIV/AIDS Crisis among African Americans. Internal reviews should be completed for the Director of the Domestic Policy Council within 60 days and include detailed plans, appointed personnel, and funding identified or requested to carry out such plans.

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[2] CDC website: http://www.cdc.gov/hiv/topics/aa/resources/reports/heightendresponse.htm#t3-1. Accessed December 17, 2008.

Process by which the Recommendation can be implemented: Executive Order to the U.S. Departments of Health and Human Services, Housing and Urban Development, Justice, Labor, Veterans Affairs, Interior, Education, Agriculture, and Transportation.

Executive Office of the President

***Issue:* Accelerate and coordinate federal efforts to address growing impact of HIV/AIDS among gay men and other men who have sex with men (MSM)**

Explanation: The majority of new HIV infections in the United States (more than 57%) are among gay, bisexual and other men who have sex with men (MSM). MSM are 10-30 times more likely to get HIV than heterosexual men and the population at large, in the US and worldwide. In the new HIV incidence estimate, MSM are the only group showing rising rates in the past decade and thus are a major factor in the inability to bring down the rate of infection in our nation.

The resources dedicated to HIV prevention and research among gay men, however, are not proportionate to their centrality in the epidemic. CDC reports that fewer than 8% of gay and bisexual men surveyed in 15 cities received group-level HIV prevention services and only 15% received individual-level interventions. Thus, 85-92% of all MSM at risk for HIV are not receiving the currently most effective prevention support. This critical failure affects MSM of all races and ethnicities, but is most dire among Black, Latino, American Indian and Asian and Pacific Islander gay men whose risk of acquiring HIV is several times higher than the already sky-high risk for white gay men.

The historic underinvestment in research on HIV prevention on MSM has led to a scarcity of accepted interventions for gay men. Only four of the 30 "best-evidence" prevention interventions in the CDC's current updated "Compendium of Evidence-based Interventions" and only four of the 17 packaged "DEBIs" (shorthand for a CDC project called Diffusion of Effective Behavioral Interventions) are directed at MSM. State and local health department and community-based organization prevention programs are strongly encouraged, if not outright required, to use these interventions in their federally- funded programs.

The 2008 International AIDS Conference, with an unprecedented focus on MSM, stressed the need to move the social and structural context, environment and interventions into the center of the AIDS response in order to confront the role of stigma and other social determinants of the epidemic. However, there are no structural and social interventions in the CDC's Compendium of Effective Intervention or DEBIs, nor anything in the public portfolios of the CDC, NIH, SAMHSA or HRSA that confront and target homophobia-related stigma as a key barrier to ending the US HIV epidemic.

***Requested Action:* The President should issue an executive order requiring the Department of Health and Human Services to develop a comprehensive agenda to address the high and growing incidence of HIV in gay men, including research and programs to identify and address the role of stigma in the persistence of the epidemic.**

Recommendation: No later than April 1, 2009, the President should issue an Executive Order to the Department of Health and Human Services, requesting a detailed internal review of activities that the Department will undertake to address the high and growing incidence of HIV in gay men and other MSM. Within 60 days these internal reviews should be completed and sent to the Director of the Domestic Policy Council and shall include detailed plans and expected outcomes, personnel responsible for implementation and a funding strategy. .

Process by which the Recommendation can be implemented: Executive Order to the U.S. Departments of Health and Human Services.

Executive Office of the President

***Issue:* Eliminate all discriminatory HIV-specific exclusions of individuals from who work in or with federal agencies.**

Explanation: Individuals with HIV are categorically excluded from certain federal agency programs and employment, solely on the basis of their HIV status. Section 501 of the Rehabilitation Act, 29 U.S.C. § 794a(a)(1), prohibits federal agencies from discriminating based on disability in employment, and Section 504 of the Rehabilitation Act, 29 U.S.C. § 794, prohibits any "program or activity" receiving federal financial assistance from discriminating against an otherwise qualified individual on the basis of disability. However, certain federal agencies – including the Department of State, the Department of Labor, and the Department of Defense – maintain categorical bans against employees or job training applicants with HIV, and certain federal agencies – including the Department of State and the Department of Defense – have imposed similar categorical restrictions on private contractors working for these agencies. Prospective employees and job training candidates should not be required to litigate against the government simply to be considered for jobs for which they are qualified.

Requested Action: **Executive Order.**

Recommendation: Issue an Executive Order that requires all federal agencies, including all civilian jobs with the Department of Defense, to comply with the Rehabilitation Act by barring them specifically from using HIV infection as a basis for a categorical exclusion of, or other medically-unwarranted restrictions on, applicants, candidates, or employees from any position including job training programs; and requires that all federal agencies must individually assess whether an individual with HIV can perform the functions of the position or activity and whether a reasonable accommodation can be made for that person if necessary to permit the individual's employment or inclusion. A sample Executive Order is attached.

Process by which the Recommendation can be implemented: The President has the authority to issue such Executive Orders.

Executive Office of the President

Issue: **Accelerate the conduct of research and implementation planning for pre-exposure prophylaxis (PrEP) for HIV prevention.**

Explanation: Clinical trials of pre-exposure prophylaxis (PrEP) are currently underway or planned in several countries in Africa, Asia, Latin America and North America. These studies are looking at the safety and efficacy of PrEP, a strategy in which HIV negative people could take an antiretroviral drug (ARV), or combination of ARVs, on a regular basis in the hopes of reducing their risk of acquiring HIV. The CDC and NIH are the leading funders of this research which is expected to obtain results much sooner than other biomedical HIV prevention interventions, including vaccines and microbicides.

The new annual HIV incidence estimates confirm that gay men and other MSM represent a larger, and growing, share of annual new HIV infections in the United States than any other risk group. A domestic CDC-sponsored safety trial of PrEP in gay men and other men who have sex with men (MSM) is scheduled to provide results in 2009, and it is possible that an NIH-sponsored efficacy trial of PrEP in this population could have interim results as soon as late 2009 or early 2010. With these results forthcoming, there is no time to lose in planning for optimum delivery of PrEP at home and abroad should it prove safe and effective. Delivery of PrEP could have a powerful impact on the domestic epidemic. There is, therefore, an urgent need for CDC to work with other trial sponsors, policy makers, health care providers, and communities to design a highly strategic approach for delivery of PrEP in the US.

Requested Action: **The President should issue an executive order requiring the CDC and NIH to develop a joint, comprehensive PrEP research agenda and the CDC to develop all necessary plans for implementing PrEP should it be proven safe and effective.**

Recommendation: No later than April 1, 2009, the President should issue an Executive Order to the Secretary of Health and Human Services requesting a detailed internal review of PrEP research and planning activities of the Centers for Disease Control and Prevention and the National Institutes of Health. Internal reviews should be completed within 60 days and include detailed plans, timelines and funding identified or requested to implement such plans.

Process by which the Recommendation can be implemented: Executive Order to the U.S. Departments of Health and Human Services.

Section 1
Tab B

Executive Office of the President
Office of Congressional Liaison

Executive Office of the President
Office of Congressional Liaison

***Issue:* Support extension of the Ryan White CARE Act for three years.**

Explanation: In December of 2006, the Ryan White Programs were reauthorized for a three year period and contained a sunset clause. Without action, the Programs will expire on September 30, 2009. See Public Law 109-415.

The reauthorization implemented many significant changes including changing the distribution formulas from estimated living AIDS cases to actual living AIDS cases and the inclusion of living HIV cases, a core services requirement, and provisions regulating unobligated funds. The impact of these changes has not been fully analyzed as sufficient data is currently unavailable.

With a few exceptions, most HIV/AIDS organizations agree that the current Ryan White Programs must be extended for a period of three years. We believe that supporting an extension is the most prudent course of action given the many congruent factors impacting the legislative future of the Programs.

***Requested Action:* Send letter to Senate Health, Education, Labor and Pensions (HELP) and House Energy and Commerce Committee stating the President's support for a three year extension of the Ryan White CARE Act.**

Recommendation:
1. The Senate committee of jurisdiction for the Ryan White Programs is the Senate Health, Education, Labor and Pensions (HELP) Committee chaired by Senator Ted Kennedy with Ranking Member Michael Enzi. The House committee of jurisdiction is Energy and Commerce Committee chaired by Representative Henry Waxman with Ranking Member Joe Barton. Both committees should be sent a letter stating that "the President and his advisors support extending the Ryan White CARE Act for three years due to the lack of full data resulting from the significant changes to the Ryan White Program created by the reauthorization in 2006. These changes include the distribution formulas from estimated living AIDS cases to actual living AIDS cases and the inclusion of living HIV cases, a core services requirement, and provisions regulating unobligated funds. Sufficient data to understand the impact of these changes is not currently available and the program should maintain its stability and purpose as the payer of last resort as health care reform proceeds."

2. The Office of Congressional Liaison and the Department of Health and Human Services should work with the HIV/AIDS community on suggested small changes that the community will recommend for the extension. A list is currently being developed.

3. The Office of Congressional Liaison should work with the Human Resources Services Administration (HRSA) HIV/AIDS Bureau to identify and develop internal recommendations for Congress. Such recommendations should both clearly improve the program and be limited to actions which may be accomplished within the format of an extension.

Process by which the Recommendation can be implemented:
1. Such a letter could be written directly by the Executive Office of the White House via the Office of Congressional Liaison. Another option is for Secretary Tom Daschle of the Department of Health and Human Services to write such a letter on behalf of the President which could then be delivered via the Office of the Congressional Liaison.

2. The Office of Congressional Liaison and the Department of Health and Human Services should meet with the Ryan White Work Group of the Federal AIDS Policy Partnership to receive community recommendations. The Co-chairs of the Ryan White Working Group are William McColl, Political Director for AIDS Action available at 202-530-8030 ext. 3096 or wmccoll@aidsaction.org and Ann Lefert, Associate Director of Government Relations, at the National Alliance of State & Territorial AIDS Directors available at (202) 434-7138 or alefert@nastad.org.

3. The HRSA HIV/AIDS Bureau can be contacted at:

Parklawn Building
5600 Fishers Lane, Room 7-05
Rockville, MD 20857
(301) 443-1993

The current Associate Administrator is Deborah Parham Hopson, Ph.D.

Section 1
Tab C

Executive Office of the President
Office of Management and Budget

Executive Office of the President
Office of Management and Budget

***Issue*: Increase funding for the HIV/AIDS domestic portfolio by increasing the Function 550/discretionary budget allocation (health) to the amount requested by the Coalition for Health Funding in the Fiscal Year 2010 (FY10) Budget.**

Explanation: The HIV/AIDS funding portfolio at the Department of Health and Human Services operates within the United States healthcare structure. An increase in HIV/AIDS funding may be accomplished by increasing the Function 550/discretionary budget allocation (health) to the amount requested by the Coalition for Health Funding in the Fiscal Year 2010 (FY10) Budget. The Function 550 request number will be finalized in January and represents the efforts of 50 national organizations that work in a nonpartisan fashion to ensure that health discretionary spending remains highly visible as Congress and the Administration set federal budget priorities. The entire healthcare community requires increased funding and we support that goal. Once the healthcare portfolio is increased, the HIV portion of the Department of Health and Human Services budget should be increased as follows:

Prevention is critical in the HIV epidemic. The number of people living with HIV in the U.S. is rising while HIV prevention funding has been cut the past six years. Therefore the Centers for Disease Control and Prevention need increases in funding for HIV Prevention and Surveillance Branch by $877 million in FY10 for a total of at least $1.569 billion, and the Division of Adolescent and School Health (DASH), needs an increase of $26.4 million in FY10 for a total of at least $66.6 million. We also request at least $50 million in new funding be allocated toward fulfilling the goals of establishing medically accurate and age appropriate comprehensive sexuality education for all school aged children.

Treatment for those living with HIV and AIDS is vital to their health and well being. Treatment is also an important prevention tool. The Ryan White CARE Act provides treatment for those living with HIV who do not have any other access to care and treatment. Increase overall funding for the Ryan White Program by $614.49 million in FY10 for a total of at least $2.78 billion. The individual parts need the following increases: Part A, which provides funding to 56 metropolitan areas, needs $213 million in FY10 for a total of at least $840 million. Increase funding for the Part B Base, which provides funding to states and territories by $95 million in FY10 for a total of at least $482 million. Increase funding for the AIDS Drug Assistance Program (ADAP), (included in Part B) which provides lifesaving drug treatment, by $134.6 million in FY10 for a total of at least $943.5 million. In Part C increase funding for the 363 directly funded clinics, by $100.5 million in FY10 for a total of at least $299 million. In Part D increase funding for services to women, children, youth and families, by $48.8 million in FY10 for a total of at least $122.5 million. Increase funding in Part F for the AIDS Education and Training Centers, which train health care providers by $15.9 million in

FY10 for a total of at least $50 million. Also increase funding in Part F for the Dental Reimbursement Program, by $6 million in FY2010 for a total of at least $19 million.

AIDS research supported by the National Institutes of Health (NIH) is critical for new drug development, diagnostics and disease prevention, including behavioral research and research on vaccines and microbicides. Include in the President's FY2010 Budget Request a total of at least $34 billion for NIH which represents a 15% increase over the FY2008 funding level. The overall 15% increase to NIH should include for AIDS research a minimum of $3.4 billion; for TB research a minimum of $209 million; for hepatitis B research a minimum of $48 million; and for hepatitis C research a minimum of $124 million.

HIV and AIDS is increasingly becoming a disease of racial and ethnic groups in the United States, especially those who are living in poverty. To work to eliminate the health disparities in HIV and improve health outcomes of racial and ethnic populations, funding for the Minority AIDS Initiative, which supports programs across eight agencies needs to be increased by $223 million in FY10 for a total of at least $610 million.

Requested Actions:
1. Increase the Function 550/discretionary budget allocation (health) to the amount requested by the Coalition for Health Funding in the Fiscal Year 2010 (FY10) Budget. The number is currently being developed and will be available in January. The Coalition for Health Funding can be contacted via Executive Director, Marcia Mabee, MPH, PhD, at 703-709-3001.

2. Include the above funding requests related to HIV/AIDS in the Department of Health and Human Services (HHS) Budget request to Congress for all of the HIV programs at HHS.

Process: Direct Office of Management and Budget to include the above amounts in the budget request of the President for Fiscal Year 2010.

Executive Office of the President
Office of Management and Budget

***Issue*: Increase funding in the housing portfolio at the Department of Housing and Urban Development for the Housing for People with AIDS (HOPWA) program by $169.9 for at least $470 million.**

Explanation: The only federal program dedicated to the housing needs of persons living with HIV/AIDS and their families, HOPWA provides housing assistance and related services for low-income people with HIV/AIDS and their families. HOPWA funds are used for a wide range of housing, social services, program planning, and development costs, including the acquisition, rehabilitation, or construction of housing units; costs for facility operations; rental assistance; and short-term payments to prevent homelessness. HOPWA funds also may be used for health care and mental health services, chemical dependency treatment, nutritional services, case management, assistance with daily living and other supportive services. Crucially these services help people living with HIV to maintain stability in their treatment program and contribute to people living with HIV having longer, healthier lives.

***Requested Action*: Include a $169.9 million increase for a total of at least $470 million in your FY10 Department of Housing and Urban Development Budget request to Congress for the HOPWA program.**

Process: Direct Office of Management and Budget to include the above amount in the budget request of the President for Fiscal Year 2010.

Executive Office of the President
Office of Management and Budget

Issue: **Support lifting the ban on use of federal funds for syringe exchange programs in the Fiscal Year 2010 budget and elsewhere.**

Explanation: In 2006, the year for which most recent data is available, 15,872 HIV/AIDS cases reported to the CDC were attributable to direct risk factors associated with injection drug use. Eight federal studies have concluded that syringe exchange reduces HIV infection and does not increase drug abuse. A 2005 study found that HIV infection rates decreased by 5.8% per year in cities with syringe exchange programs compared to a 5.9% increase in cities without syringe exchange. In December 2007, Congress and President Bush ended the ban on Washington D.C.'s use of its own local tax revenues to fund syringe exchange. President-Elect Barack Obama has committed to ending the ban on the federal funding of syringe exchange programs in his campaign platform and transition plans.

Syringe exchange is among the most effective prevention efforts for HIV/AIDS. President-Elect Obama's commitment to the promotion of sound public health policies can be furthered by lifting of the ban on the use of federal funding for syringe exchange programs which until now, has been added annually to the President's budget (and the Labor Health and Human Services appropriation bill). Removing the ban on funding will allow for the broader implementation and scale up of evidence-based, proven effective, HIV prevention programs for injecting drug users.

***Requested Actions*:**
1. Direct Office of Management and Budget to remove any requirements for maintaining a federal ban on syringe exchange in the budget request of the President for Fiscal Year 2010 and include a statement in the President's FY10 budget request to Congress requesting removal of all language that bars federal funds from being used in syringe exchange programs.
2. Publicly support Congressman Jose Serrano's (D-NY) "Community HIV/AIDS and Hepatitis Prevention Act" (HR 6680 in the 110th Congress) which would effectively remove all language in the U.S. code seeking to ban the use of federal funds for syringe exchange programs.

Process:
1. Direct Office of Management and Budget to remove any requirements for maintaining a federal ban on syringe exchange in the budget request of the President for Fiscal Year 2010 and include language in the budget specifically requesting Congress to remove the ban from the Labor Health and Human Services appropriation bill
2. Send a letter in support of the "Community HIV/AIDS and Hepatitis Prevention Act" to Representative Jose Serrano.

Executive Office of the President
Office of Management and Budget

***Issue*: Support evidence-based sexuality education by discontinuing funding for abstinence-only until marriage programs.**

Explanation:
Despite young people's high risk of STD infection, federal funding supports abstinence only education programs which have consistently proven ineffective. In a 2007 government study of four abstinence only programs, researchers found that youth enrolled in abstinence only programs had sex at the same rate, had the same number of sexual partners, and used condoms at the same rate as the non program youth. For both the group enrolled in the program and the control group, the average age of first intercourse was 14.9. The program youth, however, were less knowledgeable about potential health risks of STDs and were less likely to report that condoms work to protect from STDs. Twenty one percent of those receiving abstinence only education reported that condoms are never effective in preventing HIV. Of the program group, over half of the participants had sex in the last 12 months. Abstinence only education has been scientifically proven not to stop or even decrease sexual activity, only to decrease knowledge of safe sexual practices and STDs .

Youth need to have a comprehensive and medically accurate understanding of their options, from abstinence to safer sex, to make informed and safe choices. President – Elect Obama has stated that he intends to make the most effective use of federal dollars and promote sound public health policies. He can do so by supporting evidenced-based sexuality education and by discontinuing funding for abstinence-only until marriage programs, including those funded through: the Community-Based Abstinence Education (CBAE) and redirecting such funding to the CDC Division of Adolescent and School Health (DASH) to support comprehensive evidence-based prevention programs.

***Requested Action*: Discontinue funding for abstinence-only until marriage programs, including those funded through: the Community-Based Abstinence Education (CBAE). Redirect such funding to CDC-DASH to support comprehensive evidence-based prevention programs.**

Process:
Direct Office of Management and Budget to discontinue funding for abstinence-only until marriage programs, including those funded through: the Community-Based Abstinence Education (CBAE). Such funds should be redirected to CDC-DASH to support comprehensive evidence-based prevention programs.

Executive Office of the President
Office of Management and Budget

Issue: **Eliminate federal support for failed and ideologically driven abstinence-only-until-marriage programs.**

Explanation: The Bush Administration has promoted dangerous, ineffective abstinence-only-until-marriage programs that contain inaccurate information about sexual and reproductive health and discriminate against those who cannot or choose not to marry. Since 1998, federal policymakers have allocated more than $1.3 billion taxpayer dollars for abstinence-only-until-marriage programs, despite overwhelming evidence that this massive federal expenditure has failed completely to achieve its stated goals. The President's budget should eliminate funding for all abstinence-only-until-marriage programs by (i) abolishing the abstinence-only program within the Title V MCH Services Block Grant; (ii) abolishing the Community-Based Abstinence Education program; (iii) de-linking the Adolescent Family Life Act (AFLA) from the A-H definition in the Title V abstinence-only program; and (iv) tightening AFLA program eligibility in order to end funding for all programs that promote an abstinence-only-until-marriage approach.

Requested Action: **Zero out all funding for abstinence-only-until-marriage programs in the President's Fiscal Year 2010 Budget to Congress**

Recommendation and Process by which the Recommendation can be implemented: The President should signal in the *Budget of the United States Government—Appendix* his intention to end funding for abstinence-only programming. Specifically:

(i) Abolishing Section 510(b)(2) of Title V of the Social Security Act

"This legislative proposal provides for **[**an extension**]** *the elimination* of the Title V abstinence education program, which provides grants to States to implement abstinence-only education programs."

(ii) Abolishing the Community-Based Abstinence Education Program

[*Provided further*, That **[**$110,836,000**]** *$136,664,000* shall be for making competitive grants to provide abstinence education (as defined by section 510(b)(2) of the Social Security Act) to adolescents, and for Federal costs of administering the grant: *Provided further*, That grants under the immediately preceding proviso shall be made only to public and private entities which agree that, with respect to an adolescent to whom the entities provide abstinence education under such grant, the entities will not provide to that adolescent any other education regarding sexual conduct, except that, in the case of an entity expressly required by law to provide health information or services the adolescent shall not be precluded from seeking health information or services from the entity in a different setting than the setting in which abstinence education was provided: *Provided further*, That within amounts provided herein for abstinence education for adolescents, up to **[**$10,000,000**]** *$10,000,000* may be available for a national abstinence education campaign: *Provided further*, That in addition to amounts provided herein for abstinence education for adolescents, **[**$4,500,000**]** *$4,410,000* shall be available from amounts

available under section 241 of the Public Health Service Act to carry out evaluations (including longitudinal evaluations) of adolescent pregnancy prevention approaches:**]**

Program and Financing (in million of dollars)

Identification code 75-1536-0-1-506 2008 actual 2009 est. 2010 est.

Obligations by program activity:

01.30 Abstinence education (discretionary) 109 137 0

(iii) De-linking the Adolescent Family Life Act (AFLA) from the A-H definition in the Title V Abstinence-Only Program

The President should ask Congress to remove appropriations language that—by waiving Congressionally approved earmarks under section 2010(c) of title XX of the Public Health Service Act and tying prevention service demonstration grants to section 510(b)(2) of title V of the Social Security Act—distorts the original intention of AFLA: **[**"*Provided*, That of the funds made available under this heading for carrying out title XX of the Public Health Service Act, $13,120,000 shall be for activities specified under section 2003(b)(2), all of which shall be for prevention service demonstration grants under section 510(b)(2) of title V of the Social Security Act, as amended, without application of the limitation of section 2010(c) of said title XX"**]**

Section 1
Tab D

Department of Health and Human Services
Office of the Secretary

Department of Health and Human Services

Issue: **There is a paucity of HIV primary care providers—physicians, nurse practitioners, and physician assistants to provide the continually evolving and complex care and treatment needed by persons with HIV/AIDS in the U.S.**

Explanation: As the first generation of HIV clinicians nears retirement, a serious HIV workforce crisis looms and is already evident in some areas of the U.S. Numerous studies document that people with HIV/AIDS experience better treatment outcomes and receive more cost effective care when managed by experienced HIV medical providers. The lack of qualified HIV providers will soon serve as a serious barrier to accessing effective HIV care. A recent survey of Ryan White Part C medical clinics conducted by the HIV Medicine Association and the Forum for Collaborative HIV Research found that nearly 70% of the clinics across the country reported significant challenges in recruiting and retaining qualified HIV medical providers. The dearth of providers is due to a number of factors: treatment for HIV disease is extremely complex and demanding; HIV disease disproportionately affects low-income persons of color and people with other serious medical conditions such as hepatitis C and mental illnesses; and reimbursement for HIV treatment is significantly lower that the actual cost of delivering care.

Requested Actions: 1) Conduct a national study of the HIV medical workforce—physicians, nurse practitioners and physician assistants—that assesses the capacity of the HIV medical workforce to respond to the medical needs of persons living with HIV/AIDS on a regional and national basis; evaluate reimbursement through Medicaid and other payors; and evaluate the impact of HIV provider shortages on patient outcomes. Develop clinical provider need projections based on the potential impact of expanded HIV screening to identify those currently unaware of their HIV status. 2) Ensure that HIV primary care capacity is addressed in the context of broader primary medical care provider capacity issues in the context of national health care reform. 3) Include HIV medical providers and their representatives in relevant policy planning discussions relevant to medical workforce issues and national health care reform.

Recommendations: 1) Fund a national study of the HIV medical workforce through HHS discretionary funds or as an alternative include a proposal for a $1 million study of the HIV medical workforce in the President's FY10 budget proposal. 2) Address HIV medical workforce issues in the context of health care reform and efforts to address general primary care shortages.

Process by which the Recommendation can be implemented: The President can include this recommendation in his 2010 budget proposal or the Secretary can authorize the use of discretionary funds for the study.

Section 1
Tab E

Department of Health and Human Services
Administration for Children and Families

Department of Health and Human Services
Administration for Children and Families

***Issue:* Medically inaccurate information being disseminated by abstinence-only-until-marriage grantees**

Explanation: The need to end all abstinence-only-until-marriage programming is both well documented and needed immediately. However, it is likely that in the very near term, some programming will continue and requires additional oversight to ensure these programs are not providing medically inaccurate information and denigrating the role of condoms and other forms of barrier contraceptives in promoting responsible behaviors. The need for this effort is based on extensive evidence, including the 2007 report on this issue from the House of Representatives Committee on Oversight and Government Reform and the 2008 oversight hearing in the same committee on these programs, that uncovered severe violations of basic medical facts and public health ethics being carried out with taxpayer dollars in these funded programs.

***Requested Action:* Immediate review of grantees to ensure medically accurate information is being provided.**

Recommendation: The Secretary of Health and Human Services should direct the Associate Commissioner of the Family and Youth Services Bureau to conduct an immediate review of all materialized used by grantees to ensure none of them are communicating and utilizing medically inaccurate information, including inaccurate information about the benefits and side effects of condoms and other forms of contraception.

Process by which the Recommendation can be implemented: There is an effort already underway within HHS to respond to Congressional demands on this issue, including the hiring of a position to review materials of grantees. However, early indications suggest that the existing inquiry is much too narrow and needs to be reassessed.

Section 1
Tab F

Department of Health and Human Services
Centers for Disease Control and Prevention

Department of Health and Human Services

Centers for Disease Control and Prevention

Issue: **Remove HIV as a "communicable disease of public health significance" for entry into the United States.**

Explanation: As part of the reauthorization of PEPFAR, (the United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008), signed on July 30, 2008, the Congress removed language in the Immigration and Nationality Act (INA) that explicitly prohibited HIV-positive non-citizens from entering the United States without a visa waiver. However, current CDC regulations governing communicable diseases of public health concern continue the HIV prohibition.

The Department of Homeland Security issued an interim final rule that streamlines the issuance of short-term non-immigrant visas for people who are HIV-positive. The CDC needs to revise its recommendations and remove HIV from the list of communicable diseases. As a result of inclusion on this list, people living with HIV have been and continue to be ineligible to receive a visa to enter the U.S. – whether for vacation, employment, to attend a conference or for any other reason. HIV positive people have also been ineligible to obtain lawful permanent resident status by adjustment of their immigration status.

Under the authority of section 212(a)(1)(A) of the Immigration and Nationality Act (INA) and section 325 of the Public Health Service Act, the Secretary of Health and Human Services promulgates regulations outlining the requirements for the medical examination of aliens and a list of any "communicable disease of public health significance" that make aliens ineligible for entry into the United States. HIV is currently included in this list of communicable diseases as defined in 42 CFR part 34: Medical Examination of Aliens. CDC is proposing to remove HIV as a "communicable disease of public health significance" in 42 CFR part 34.2 (b)(4).

A notice of proposed rulemaking was sent from HHS to OMB in late November, 2008, but to date it has not been published.

Requested Action: **The CDC should issue proposed regulations to remove HIV from the list of "communicable diseases of public health significance" for travel and immigration into the United States. Once the proposal has been issued for public comment, the comments should be analyzed and the regulation finalized as quickly as possible.**

Recommendation: The Administration should direct the Secretary of Health and Human Services to promptly publish in the Federal Register an interim rule, revising the definition of "communicable diseases of public health significance," 42 C.F.R. § 34.2(b), to delete the current references to HIV infection and other sexually transmitted diseases that are not a risk to citizens through casual contact. The proposed rule drafted by HHS,

should be reviewed to ensure that it accomplishes the goal of removing HIV from the list of communicable diseases of public heath significance and the supporting analysis is acceptable. If the proposed rule has been published, comments should be analyzed and a final rule published as soon as possible.

Process by which the Recommendation can be implemented: The CDC Division of Global Migration and Quarantine and the National Center for HIV, STD and TB Prevention have jointly developed the proposed regulation. The Office of the U.S. Global AIDS Coordinator at the State Department has also been extremely involved. HHS should determine the status of the proposed regulation and work with the affected parties to publish and finalize.

Section 1
Tab G

Department of Health and Human Services
Centers for Medicare & Medicaid Services

MEDICAID

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Issue: **Medicaid coverage for routine HIV testing and counseling.**

Explanation: In September 2006, the Centers for Disease Control (CDC) recommended voluntary opt-out HIV testing as part of routine medical care for people ages 13 to 64 in all health care settings. It is estimated that 21 percent or 231,000 people in the United States are HIV positive but are unaware of it. Routine HIV screening reduces the number of new infections—people who know their HIV status are less likely to engage in behaviors that could transmit the virus. Routine screening also fosters early diagnosis which improves patient outcomes. Despite the availability of innovative HIV therapies that have made HIV a chronic and manageable condition, many people with HIV are diagnosed late in their illness. In 2005, 38 percent of Americans received an AIDS diagnosis within one year of testing HIV positive.

The CDC recommendations have been endorsed by many professional societies, including the American Academy of Pediatrics, American College of Emergency Physicians, American College of Physicians, American College of Physicians and American College of Obstetricians and Gynecologists. One of the significant barriers to implementing CDC's 2006 recommendations has been that Medicaid programs across the country are not covering routine HIV testing. It has been estimated that among those recently diagnosed with HIV, more than 22 percent were already covered by Medicaid.

Requested Action: **CMS should prepare and send a "Dear State Medicaid Director" letter encouraging states to provide routine HIV/AIDS screening, outside the primary diagnosis, to Medicaid eligible individuals.**

Recommendation: The letter could be modeled after the "Dear State Medicaid Director" letter that was issued in September 1995 which encouraged implementation of the CDC's previous HIV screening recommendations for pregnant women.
http://www.cms.hhs.gov/smdl/downloads/smd091095.pdf

Process by which the Recommendation can be implemented: The CMS Center for Medicaid and State Operations should work with the CDC Division of HIV/AIDS Prevention on the development of this letter.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Issue: **Issue a final rule for Medicaid case management services that rescinds harmful provisions in the interim final rule that became effective in March 2008.**

Explanation: An interim final rule making changes to the Medicaid case management and targeted case management (TCM) benefits was issued in December 2007 becoming enforceable in March 2008. It is currently subject to a moratorium until April 2009. Case management services assist individuals in gaining access to needed medical, social, educational and other services. Forty-nine states plus the District of Columbia provide targeted case management services to various groups. The new rules implemented provisions of the Deficit Reduction Act of 2005 (DRA), but went well beyond the statutory changes to restrict access to case management and restrict who could provide case management services.

Requested Action: **Issue a final rule effectively withdrawing provisions that are more restrictive than the statutory requirements of the DRA.**

Recommendation: CMS could issue a final rule that eliminates the harmful provisions in the interim final rule. The interim final rule limits state flexibility by prohibiting a state from providing a beneficiary with more than one case manager even when the complexity of the beneficiary's condition demands the expertise of more than one program. In most cases, having one case manager would be beneficial to avoid duplication. But, if a beneficiary has multiple conditions — for example HIV/AIDS, mental illness and an intellectual disability — no one case manager may be able to coordinate housing, health care, and social needs across multiple systems. Federal rules could establish a general standard of permitting only one case manager per person, but this must provide for exceptions including the presence of multiple complex conditions, or special circumstances such as victim of domestic violence, which may require specialized case management. A final rule should also eliminate all provisions in the interim final rule that restrict the amount of time individuals can receive transition assistance and that impose new burdens on states and case management providers. Specifically, we recommend:

- Rescind in its entirety § 440.169(c);
- Revise § 441.18(a)(8)(viii)(A) to read, "Specify that the time period that case management may be provided in an institution must not exceed an individual's length of stay."; and,
- Rescind in its entirety § 441.18(a)(8)(viii)(E).

The interim final rule takes away state flexibility to efficiently manage the Medicaid program. The rule arbitrarily restricts state flexibility to determine payment methodologies in a way that could make Medicaid payments less efficient. We

recommend rescinding all requirements that impinge on longstanding state flexibility to determine their payment methodologies for case management services.

Process by which the Recommendation can be implemented: The Center for Medicaid and State Operations (CMSO) within the Centers for Medicare and Medicaid Services (CMS) is responsible for developing federal rules pertaining to state operation of their Medicaid programs. CMSO could develop and promulgate a final rule that responds to public comments already solicited in early 2008.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Issue: **Clarify that the Medicaid statute does not permit hard caps on medically necessary prescription drugs.**

Explanation: A number of states place limits on the number of prescriptions that can be dispensed in a particular month in their Medicaid programs, but these limits can be breached with clinical justification. A small number of states, however, have imposed hard limits, and do not permit drugs to be dispensed above the limit, even with clinical justification. This policy is disproportionately harmful to Medicaid beneficiaries with HIV/AIDS. Of the 3-5 states with hard caps, the limit is set at 3-4 drugs per month. Some antiretroviral therapy regimens, however, utilize 4 or more medications in the antiretroviral regimen alone. This is especially common for persons with HIV/AIDS who have used antiretroviral medications in the past and have failed on previous regimens. Further, individuals with HIV require a broad range of other pharmaceuticals, including statins, insulin and drugs to manage diabetes, and drugs used to treat depression and other forms of mental illness.

Requested Action: **Establish a policy interpreting subsection 1927(d) of the Social Security Act to prohibit hard caps on prescription drugs.**

Recommendation: Subsection 1927(d) of the Social Security Act specifies permissible restrictions on the coverage of prescription drugs. This subsection authorizes states to deny coverage for drugs in certain circumstances, such as for indications that are not medically accepted. This subsection also gives states the discretion to deny coverage for the "excludable" drugs, and specifies requirements for formularies and prior authorization programs. Whereas subsection 1927(d)(6) authorizes limits needed to minimize waste and prevent fraud, this limitation should not apply to cases where individuals have documented a clinical need for drugs above the cap, such as through prior authorization.

Process by which the Recommendation can be implemented: CMS can issue policy guidance interpreting the Medicaid statute to require exceptions to any drug caps in cases of medical necessity. Such guidance should include an effective date when states with these caps must come into compliance with this new policy.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Issue: **Issue new Medicaid waiver policy guidance.**

Explanation: The Secretary of HHS has broad authorities under the Social Security Act to waive provisions of the Medicaid law. The Medicaid statute has an extensive array of essential beneficiary protections that are critical to protecting the health and welfare of vulnerable Medicaid beneficiaries. The Secretary of HHS has discretionary authority to waive some requirements of federal law. While waiver programs can be beneficial for covered individuals, they also have the potential to take away critical protections. In recent years, waivers have been approved that do not meet the minimum standard of care for HIV…and that would be insufficient to meet the needs of other populations with disabilities or chronic conditions. For example, Arkansas received a waiver to expand access to Medicaid, but the waiver population's benefit package included a 3 drug per month limit. Prior to serving as Secretary, Governor Leavitt of Utah received a waiver to expand access to Medicaid that reduced services for existing populations and provided limited benefits to the expansion population—that did not provide for access to specialty care or inpatient hospital services. HHS should signal that these types of programs do not meet minimum standards and would not be approvable in the Obama Administration.

Requested Action: **Issuance of waiver guidance**

Recommendation: CMS could provide new waiver guidance for states that specifies minimum beneficiary protections that will be required regarding the scope of coverage and other critical issues. While not limiting the Secretary's waiver approval authority, CMS could develop waiver guidance that describes parameters of waiver applications that would receive a streamlined review. If states submit waivers that meet minimum benefit standards, satisfies public process requirements, and meet other requirements, they would be promised a quick review of their application.

Process by which the Recommendation can be implemented: CMS has the authority to issue sub-regulatory guidance that provides a waiver template and checklist to states to ensure that their proposals meet federal minimum standards.

Section 1
Tab H

Department of Health and Human Services
Centers for Medicare & Medicaid Services

MEDICARE

Department of Health and Human Services
Centers for Medicare and Medicaid Services

Issue: **Allow Expenditures made by the AIDS Drug Assistance Programs to count towards True-out-of-Pocket costs under Medicare Part D.**

Explanation: When Congress established the Medicare Part D program, drug spending by other government programs was prohibited from counting toward the calculation of so-called true out-of-pocket costs (TrOOP), with one exception, state pharmaceutical assistance programs. The Centers for Medicare and Medicaid Services (CMS) has interpreted the law such that AIDS Drug Assistance Programs (ADAPs) are not to be considered state pharmaceutical assistance programs (SPAPS) even though they are supported by significant state contributions and must ensure that they are the payer of last resort. TrOOP spending is a critical issue because it determines when "catastrophic coverage" begins. Catastrophic coverage begins when individuals with exceptionally high drug costs move through the coverage gap by spending $4,050 in out-of-pocket costs and their cost sharing falls to 5% of drug costs. TrOOP also is significant because these expenses are used to determine when individuals exit the coverage gap known as the donut hole. Because ADAP spending does not count toward TrOOP, individuals can not move out of the coverage gap and are therefore unable to access their Medicare drug formularies for approximately 9 to 10 months out of the plan year. These individuals must rely only on ADAP, which in almost all cases has a much more limited formulary than the typical Medicare plan.

Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. It makes little sense for the federal government to restrict use of state ADAP funds in this fashion. ADAPs are structurally comparable to SPAPs, and receive significant state general revenue contributions. The CMS interpretation which narrowly defines SPAPs and does not include ADAPs leaves thousands of Medicare beneficiaries living with HIV/AIDS without a comprehensive Part D benefit and requires ADAPs to pick up costs that Medicare Part D should be covering.

Requested Action: **Reinterpretation of the TrOOP provision to allow contributions from ADAPs.**

Recommendation: The Secretary of HHS in conjunction with the Administrator of CMS should reinterpret the TrOOP provision and the definition of SPAPs to allow contributions made by ADAPs to count towards TrOOP.

Process by which the Recommendation can be implemented: Promulgation of rule allowing ADAP contributions to count towards TrOOP.

Department of Health and Human Services
Centers for Medicare and Medicaid Services

Issue: **Maintain and strengthen protections for six critical classes of medications under Medicare Part D.**

Explanation: For 2006 through 2009, CMS implemented an essential consumer protection under Medicare Part D through sub-regulatory guidance that required broad formulary coverage for drugs used by some of the most vulnerable populations. Instead of requiring Part D plans to cover only two drugs per class, CMS has required Part D plans to cover "all or substantially all" drugs in six key classes (Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals, Immunosupressants). This protection was granted on an annual basis and in the past was subject to being revoked every year. The Medicare Improvements for Patients and Providers Act of 2008 included a provision (Sec. 176 – see attachment) that codified CMS authority to require Part D plans to cover all of the drugs in certain drugs classes; however, the legislation did not name the classes that are currently protected and regulations are needed to specify that coverage of all of the drugs in the six classes will continue in 2010 and beyond. This protection has been critical to ensuring that Medicare beneficiaries with HIV/AIDS and other serious conditions maintain access to lifesaving medications.

Requested Action: **Promulgate regulations that require prescription drug plans to cover all medications within the following drug classes – Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals, Immunosupressants and to cover new medications within 90 days of FDA approval. Maintain the additional protection for antiretrovirals that bars plans from applying utilization management techniques, such as prior authorization, to this drug class.**

Recommendation: Issues regulations implementing Section 176 based on Section 30.2.5 -- Six Classes of Clinical Concern of the Medicare Prescription Drug Benefit Manual – Chapter 6 Part D Drugs and Formulary Requirements (See attachment). Also online at: http://www.cms.hhs.gov/Transmittals/Downloads/R2PDB.pdf.

Process by which the Recommendation can be implemented: The Secretary has the authority to identify protected as authorized in the Medicare Improvements for Patients and Providers Act of 2008. Pub. Law 110-275. SEC. 176.

Supplemental Materials:

Current from the Current Medicare Prescription Drug Benefit Manual
30.2.5 -- Six Classes of Clinical Concern

Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant *(for prophylaxis of organ transplant rejection),* antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs

would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

Formularies must include substantially all drugs in these six categories that are FDA approved by the last CMS specified HPMS formulary upload date for the upcoming contract year. New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. **At the end of the 90 day period, these drugs must be added to Part D plan formularies.**

"Substantially all" in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions:

- multi-source brands of the identical molecular structure;
- extended release products when the immediate-release product is included;
- products that have the same active ingredient or moiety; and
- dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals);

Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees who were actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. If a sponsor cannot determine at the point of sale that an enrollee is not currently taking a drug (e.g., new enrollee filling a prescription for the first time), sponsors shall treat such enrollees as currently taking the drug.

For HIV/AIDS Drugs, utilization management tools such as prior authorization and step therapy are not employed in widely used, best practice formulary models and may not be applied under Part D to the antiretroviral drug class. Part D sponsors may conduct consultations with physicians regarding treatment options and outcomes in all cases.

Medicare Improvements for Patients and Providers Act of 2008. Pub. Law 110-275.

SEC. 176. FORMULARY REQUIREMENTS WITH RESPECT TO CERTAIN CATEGORIES OR CLASSES OF DRUGS.

Section 1860D-4(b)(3) of the Social Security Act (42 U.S.C. 1395w-104(b)(3)) is amended--

(1) in subparagraph (C)(i), by striking `The formulary' and inserting `Subject to subparagraph (G), the formulary'; and

(2) by inserting after subparagraph (F) the following new subparagraph:

`(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES-

`(i) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES- Beginning with plan

year 2010, the Secretary shall identify, as appropriate, categories and classes of drugs for which both of the following criteria are met:

`(I) Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class.

`(II) There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.

`(ii) FORMULARY REQUIREMENTS- Subject to clause (iii), PDP sponsors offering prescription drug plans shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (i).

`(iii) EXCEPTIONS- The Secretary may establish exceptions that permits a PDP sponsor of a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under clause (ii) (or to otherwise limit access to such a drug, including through prior authorization or utilization management). Any exceptions established under the preceding sentence shall be provided under a process that--

`(I) ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents); and

`(II) includes a public notice and comment period.'.

Department of Health and Human Services
Centers for Medicare and Medicaid Services

Issue: **Allow AIDS Drug Assistance Programs (ADAPs) access to Low Income Subsidy Data from CMS.**

Explanation: ADAPs are encouraged to provide wrap-around services to Medicare Part D beneficiaries who are also eligible for ADAP services. Currently, many states pay for premiums, deductibles, co-pays and other cost-sharing for Part D beneficiaries. However, CMS has not allowed access to low-income subsidy data through the *Supplement Drug Program Data Sharing Agreement* that many states have entered into. Without this data, states are unable to verify that they are paying the correct amounts for cost-sharing which puts them in danger of violating the payer of last resort requirements of the Ryan White Programs.

Requested Action: **Allow ADAPs access to Low Income Subsidy Data.**

Recommendation: The Administrator of CMS should direct the Division of Medicare Secondary Payer Policy and Operations to allow ADAPs who have entered into the *Supplement Drug Program Data Sharing Agreement* access to LIS data for ADAP-enrolled clients who are also Medicare beneficiaries.

Process by which the Recommendation can be implemented: Direction from the Administrator of CMS.

Section 1
Tab I

Department of Health and
Human Services
Health Resource Services Administration

Department of Health and Human Services
Health Resource and Services Administration

***Issue:* Withdraw the transitional housing policy that establishes a cumulative 24-month lifetime service cap per household for use of Ryan White HIV/AIDS Program funds for short-term and emergency housing assistance.**

Explanation: HRSA HIV/AIDS Bureau (HAB) Policy Notice 99-02 Amendment #1, Federal Register, February 26, 2008 (Vol. 73, No. 38) p. 10260 directs grantees on the use of Ryan White HIV/AIDS Program funds for short-term and emergency housing assistance for persons living with HIV/AIDS. Amendment #1 which took effect March 27, 2008 limits the duration of short-term and emergency housing assistance to a lifetime cumulative period of 24 months per household. In communicating the new policy to Ryan White Grantees, HRSA indicates that the policy is derived from a 2004 DHHS Office of Inspector General report (related to the situation in a specifically-identified locality in which housing assistance was provided for a number of years) instructing HRSA to "clarify the definition of short term and emergency housing assistance by establishing a time limit." ftp://ftp.hrsa.gov/hab/0801.pdf.

HRSA has been urged to reconsider the policy amendment in light of 1) the lack of affordable housing in many of the areas most severely impacted by HIV/AIDS and the significant barrier homelessness imposes on an individual attempting to adhere to HIV/AIDS care and treatment; 2) the need to maintain Ryan White transitional housing assistance as an episodic gap filler and emergency safety net; and 3) the potentially life threatening consequences associated with locking individuals out of an essential service which ignores the challenges of HIV treatment adherence and the cyclical and episodic nature of HIV disease. An arbitrary cap on access to care is counterproductive given that housing stability is of central importance to adherence and good health care outcomes. The flexibility to make housing assistance available without federally imposed time limits is essential in the context of an environment in which 1) only one in four households eligible for federal housing assistance receive it; 2) the full impact of the real estate foreclosure crisis on renters, including those with HIV and other chronic illnesses, is unknown; and 3) the wait for AIDS housing in some communities is at crisis levels.

Requested Action: The Administrator of the Health Resources and Services Administration should withdraw Policy Notice 99-02 Amendment #1. Such action would eliminate the cumulative 24 month lifetime cap on housing assistance, and in no way undermines the requirement that Ryan White grantees and community-based providers develop a written transitional housing plan. Such a plan is done in coordination with other programs, to identify permanent housing, maintain access to quality care, support long-term housing needs consistent with HRSA's concurrence in housing's essential role in access and adherence. (see March 28, 2008 letter of Deborah Parham Hopson, Assistant Surgeon General and Associate Administrator, DHHS, HRSA, HIV/AIDS Bureau to Nancy Bernstine, Executive Director, National AIDS Housing Coalition, Washington, DC.) Research documenting this connection is summarized in the attached policy paper from the National AIDS Housing Coalition, *"Examining the Evidence: The Impact of Housing on HIV Prevention and Care"*; Third Housing and HIV/AID Research Summit, March 2008. Parts of the policy notice which may remain necessary to "clarify and update certain nomenclature found in the original housing policy 99-02", but excluding the 24 month cap could be reissued.

Department of Health and Human Services
Health Resource Services Administration

Issue: **End unreasonable HRSA requirements that rebate funds must be spent prior to spending federal ADAP grant award funds.**

Explanation: Within the Ryan White CARE Act, AIDS Drug Assistance Program, Rebate model ADAPs purchase drugs via a pharmacy network and then request rebates from pharmaceutical companies to obtain the 340B program drug prices. More than half of the states are rebate model ADAPs. HRSA sent a letter to ADAPs on January 9, 2007 stating that dollars generated by rebates must be considered program income, despite the fact that the law states that rebates may not be considered part of any grant award. In general, rebate dollars should NOT be counted as program income, per Code of Federal Regulation (CFR) Title 45 Section 92.25 which states "Except as otherwise provided in regulations of the Federal Agency, program income does not include interest on grant funds, rebates, credits, discounts, refunds, etc. and interest earned on any of them." Despite language to the contrary, HHS Budget Office lawyers have determined that the language included in HRSA's January 9, 2007 letter triggers CFR Title 45 Section 92.21 and therefore trumps Title 45 Section 92.25. Title 45 Section 92.21 states "Except as provided in paragraph (f)(1) of this section, grantees and subgrantees shall disburse program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments."

The Ryan White HIV/AIDS Treatment Modernization Act requires rebate funds be put back in Part B (with preference, but not a requirement, that it be placed in ADAP). Additionally, new carryover rules require states to spend 98% of all funds prior to the end of their grant year. Given that this requires states to spend not only direct grant funds but also their rebate funds (no matter when they are received) it is likely to cause states to exceed the unobligated fund limit and thus lose certain ADAP funds permanently. While Ryan White requires rebates to be put back into the Part B Program with preference given to ADAP, rebate income should not be considered program income and could therefore accrue after a grant year has ended.

Requested Action: **Letter of exemption from the HIV/AIDS Bureau (HAB) to ADAPs.**

Recommendation: The Secretary of HHS should direct HAB to write a letter rescinding their previous correspondence of January, 2007. The letter should also clarify that "In keeping with Congressional intent and Section 2622 (d) of Public Law 109-415, rebate funds associated with Section 2616 of Public Health Service Act (42 U.S.C. 300ff-26) are exempt from 45CFR92.21."

Process by which the Recommendation can be implemented: The Department of Health and Human Services Health Resources Services Administration is responsible for this policy. The incoming Administrator of HRSA can direct HAB to write such a letter.

Department of Health and Human Services
Health Resource Services Administration
HIV/AIDS Bureau

Issue: **Rapid assessment of Ryan White CARE Act services in Puerto Rico and New Orleans .**

Explanation: Grantees administering HIV/AIDS care and treatment funds in New Orleans and in Puerto Rico (the Commonwealth of Puerto Rico) and the Municipality of San Juan) are known to be experiencing administrative difficulties that are contributing to poor outcomes for people with HIV/AIDS. In the case of San Juan there is a pending federal investigation on charges of possible corruption. HIV/AIDS advocates have expressed specific concerns about administrative ineffectiveness and mismanagement and in the case of Puerto Rico and San Juan severe shortages of qualified personnel and operating resources.

In both areas, requests for needed investigation and oversight have been documented prior to the December 2006 passage of the most recent Ryan White Program reauthorization. The community has not yet received a public evaluation of activities in the affected areas and remains frustrated by ongoing complaints from the areas and the lack of action.

Requested Action: **Perform a rapid assessment of the situation within 90 days of taking office and develop a public and comprehensive corrective action plan.**

Recommendation: Given the urgency, we ask the Administration to perform a rapid assessment of the situation within 90 days of taking office and develop a comprehensive corrective action plan that could include immediate direct federal intervention if necessary to ensure access to the U.S. standard of HIV care and treatment to low income people with HIV/AIDS through Ryan White-funded services and other federally-supported programs, such as Medicaid. Such a plan should consider facilitating immediate payment to Community Based Organizations (CBOs) of overdue reimbursements, and completely assessing the quality of patient care and long-term viability of the healthcare system. The rapid response plan should create targeted outcomes and goals, assign specific responsibility to a specific individual for meeting each targeted outcome and goal on the part of both federal government officials and grantees and establish measures of accountability for inaction.

Process by which the Recommendation can be implemented: The Department of Health and Human Services Health Resources Services Administration is responsible for the management of Ryan White Program grantees. The incoming Administrator of HRSA has the authority to initiate a rapid assessment of this dire situation and should immediately dispatch appropriate personnel to the affected areas.

Section 1
Tab J

Department of Health and Human Services
National Institutes of Health

Department of Health and Human Services
National Institutes of Health

Issue: **Supporting a Bold Agenda for HIV/AIDS Research.**

Explanation: The need for increased focus and investment in HIV/AIDS research comes at a time when the budget of the National Institutes of Health continues to dwindle. A strong, revitalized HIV/AIDS research agenda must be a critical component of a National AIDS Strategy. A National AIDS Strategy must prioritize adequate investment for HIV/AIDS research and strongly support innovative research efforts for vaccines, microbicides, biomedical and behavioral prevention methods, and improved medical treatments. It is only through the ultimate development of such interventions that the U.S. and the world will be able to end the HIV/AIDS epidemic**.**

The next Administration has an important opportunity to get the US back on track to a robust research agenda, particularly for HIV/AIDS and life-threatening related infections, including tuberculosis and viral hepatitis (hepatitis B and C). In keeping with President-elect Obama's commitment to double funding for the National Institutes of Health (NIH), the next Administration should:

Requested Action 1: **Issue a policy guidance to the Department of Health and Human Services (HHS) that ensures HHS agencies including NIH, CDC and FDA have the authority to decide the appropriate number of federal scientists to attend international meetings and conferences to advance scientific learning, exchange and networking.**

*Recommendation***:** Currently, the director of the Office of Global Health Affairs (OGHA) within HHS maintains the authority over NIH, CDC and FDA to restrict the number of federal scientists and other employees from these respective agencies that are allowed to attend international meetings and conferences, such as expert panels of the World Health Organization, and past International AIDS Conferences (IAC) held in Bangkok, Thailand (2004), Toronto, Canada (2006) and Mexico City, Mexico (2008). This policy has prevented federal scientists from presenting their discoveries and work and inhibited scientific exchange across a variety of disciplines to catalyze innovative research ideas.

Requested Action 2: **Establish a Federally Supported AIDS Research Coordinating Committee within the Office of AIDS Research to allow coordination and communication on different research efforts between NIH, CDC, NSF, DoD, VA, and other government agencies and large private foundations.**

Recommendation: Several different agencies are currently involved in supporting HIV/AIDS research in the United States. It is unclear to what extent communication among these agencies is being utilized to maximum potential.

***Requested Action 3*: Remove the ban on generating and working with new stem cell lines.**

Recommendation: AIDS research has added considerably to our knowledge of and ability to treat other diseases. Removing the ban on generating and working with stem cell lines will benefit many diseases and may be useful in formulation a cure for AIDS.

Section 1
Tab K

Department of Justice
Civil Rights Division

Department of Justice
Civil Rights Division

***Issue:* Issue Federal Guidance to Eliminate States' Unwarranted Exclusion of People with HIV from Occupational Training Schools and Licensing**

Explanation: Across the country, a patch-work of individual state laws requiring infectious or communicable disease clearance for practitioners of certain occupations, or agency interpretations of these laws, have excluded people with HIV from occupational training, licensing, and employment in professions such as barbering, massage, food services and home health care. This state-sponsored discrimination – the perpetuation of scientifically unsound restrictions on the lives and livelihoods of people with HIV – is a persistent manifestation of the stigma that limits the lives of people with HIV and undermines public health efforts to encourage HIV testing and care. It also constitutes a violation of the Americans With Disabilities Act and the Rehabilitation Act of 1973, and ignores the reasoning of the U.S. Supreme Court in *School Bd. of Nassau County v. Arline,* 480 U. S. 273, 288 (1987), by relying on "prejudice, stereotypes, [and] unfounded fear" about HIV transmission risks to categorically exclude those with HIV from training and employment for which they are qualified.

Requested Action: Department of Justice's Issuance of Guidance

Recommendation: The Administration should direct the Department of Justice to address this continuing barrier by issuing official guidance and a directive letter to state attorneys general and state agency heads, clarifying that exclusion of people with HIV/AIDS from occupational training programs and profession licensing violates the ADA and the Rehabilitation Act, and that any restrictions on program enrollment or licensing must be limited to diseases that actually pose a significant, measurable threat of occupational transmission. In addition, we recommend that this guidance be posted on the website, www.ada.gov, and endorsed and distributed jointly by the Civil Rights Division of the U.S. Department of Justice and the National Association of Attorneys General, through these agencies' joint Disability Rights Task Force.

Proposed text of guidance:

The Civil Rights Division of the U.S. Department of Justice has found that many state licensing boards and occupational training schools across the country have prohibited individuals with HIV/AIDS from pursuing careers and entering trade schools based on licensing requirements for certain occupations that exclude persons with communicable, contagious or infectious disease. Typically, licensing and hiring for these occupations will require a doctor's certification that the person is free of disease. However, most of the laws on which these requirements are based were adopted long before our current understanding of HIV transmission, and reflect outmoded understanding of communicable and infectious disease. To comply with the ADA and the Rehabilitation Act, these requirements must be interpreted to mean that the person should be free of only those diseases that have a documented impact on their ability to

participate safely in a specific training program or to perform a specific job. State licensing authorities and other officials must advise program administrators, licensing boards, and physicians to administer certification, admission and licensing requirements accordingly. More specifically, state officials must ensure that, in the drafting or administration of trade school admission or licensing laws and regulations, the term "infectious or communicable disease" shall not include human immunodeficiency virus (HIV), acquired immune deficiency (AIDS) or any other disease that similarly does not pose a documented significant risk to the health or safety of others during the performance of a particular trade or profession.

This document provides specific information about the legal requirements regarding individuals with HIV and other infectious diseases who apply for training or licensing in these or other trades and professions. It was prepared to assist state attorneys general, licensing boards, occupational training and trade school and programs, and related employers in complying voluntarily with the Americans with Disabilities Act and the Rehabilitation Act of 1973.

QUESTIONS AND ANSWERS: THE ADA AND THE ELIGIBILITY OF INDIVIDUALS WITH HIV/AIDS FOR OCCUPATIONAL TRAINING AND STATE LICENSING

Q: Are people with HIV or AIDS protected by the ADA?

A: Yes. An individual is considered to have a "disability" if he or she has a physical or mental impairment that substantially limits one or more major life activities, has a record of such impairment, or is regarded as having such impairment. Persons with HIV disease, both symptomatic and asymptomatic, are protected by the law. Persons who are discriminated against because they are regarded as being HIV-positive also are protected. For example, a person who was denied program admission or a license on the basis of a rumor or assumption that he has HIV or AIDS, even if he does not, would be protected by the law.

Q. How are state and local agencies governed by the ADA?

A. Title II of the ADA applies to state and local government entities, and protects qualified individuals with disabilities from discrimination on the basis of disability in services, programs, and activities provided by state and local government entities. Title II extends the prohibition of discrimination established by section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (section 504), to all activities of state and local governments regardless of whether these entities receive federal financial assistance.

Q: Do these laws apply to occupational training and licensing such as barbering, cosmetology and home health care assistance?

A: Yes. Under the Americans with Disabilities Act (ADA) and the Rehabilitation Act of

1973 (Rehab Act), all state and local agencies, including licensing agencies and state-supported or independently-operated trade schools and professional training programs, are prohibited from discriminating against individuals with disabilities, including individuals with HIV/AIDS. The ADA prohibits discrimination not only in hiring and firing, but in job training, licensing and all other employment-related activities. Title II of the ADA also forbids requiring an HIV test, denying a license or permit, or otherwise discriminating in the licensing/permit process solely on the basis of HIV status. Examples of discrimination against persons with HIV/AIDS would include, for example: 1) A certificate program for health aides that has a blanket policy of refusing to enroll anyone infected with the AIDS virus; 2) A cosmetology school that denies admission to a man with HIV because state cosmetology regulations require that cosmetologists be free from contagious, communicable or infectious disease

Q: Can a public entity, such as a licensing authority, or a trade school or training program, exclude a person with HIV/AIDS because that person allegedly poses a direct threat to the health and safety of others?

A: In almost every instance, the answer to this question is no. Persons with HIV/AIDS will rarely, if ever, pose a direct threat in the school or licensing context. A public accommodation may exclude an individual with a disability from participation in an activity, if that individual’s participation would result in a direct threat to the health or safety of others. "Direct threat," however, is defined as a "significant risk to the health or safety of others" that cannot be eliminated or reduced to an acceptable level by reasonable modifications to the public accommodation’s policies, practices, or procedures. The determination that a person poses a direct threat to the health or safety of others may not be based on generalizations or stereotypes about the effects of a particular disability; or about outdated views or misunderstandings about the risk posed by HIV/AIDS or other infectious diseases. It is medically established that HIV can only be transmitted by sexual contact with an infected individual, exposure to infected blood or blood products, or perinatally from an infected mother to infant during pregnancy, birth, or breast feeding. HIV cannot be transmitted by casual contact. Thus, there is little possibility that HIV could ever be transmitted in the workplace, including those involving massage therapy, cosmetology, or health services. For example, a cosmetology school’s refusal to admit a qualified applicant who is HIV-positive because of unfounded fears or beliefs about risks of occupational transmission is a violation of the ADA. Similarly an emergency technician training program may believe that an HIV-infected E.T. may pose a risk to others when performing mouth-to-mouth resuscitation. However, as current medical evidence indicates that HIV cannot be transmitted by the exchange of saliva, exclusions based on such beliefs violate the ADA.

Q. What is the responsibility under the ADA of state and local licensing authorities and training school administrators in states or localities that require a doctor’s certification that an applicant is free of disease as a prerequisite for licensing or enrollment?

A. For the purposes of occupational training and licensing requirements, the terms “infectious, communicable or contagious disease” must exclude blood-borne diseases not

transmitted through casual contact or through the usual practice of the occupation for which a license is required, in order to comply with the ADA. Consequently, licensing boards and program admissions policies must either 1) cease the requirement of certifications that an applicant is "disease-free;" or 2) amend current rules and policies to state that the certification requirement excludes diseases not transmitted through casual contact or through the usual practice of the occupation for which a license is required.

Section 1
Tab L

Department of Justice
Bureau of Prisons

Department of Justice
Bureau of Prisons

Issue: **The need to increase access by incarcerated persons to barrier protection devices, counseling, and prevention education to reduce transmission of HIV and other sexually transmitted infections (STI).**

Explanation: More than 2,000,000 persons are incarcerated in the United States at any given time and are more than four times as likely to have HIV infection as is the general population. More than 25% of the HIV-positive population in the U.S. is incarcerated at least some time during each year. Minorities account for the majority of HIV-related deaths and infections among incarcerated persons with African-American incarcerated persons being 3.5 times more likely and Hispanic persons 2.5 times more likely to die or become infected that white incarcerated persons. A significant but unknown number of new HIV/STI infections occur among incarcerated persons each year. Fewer than 5% of incarcerated persons currently have access to HIV/STI prevention education, counseling and barrier sexual protection devices. The overwhelming majority of incarcerated persons return to the community at some point, most within two years. These facts demonstrate a significant and preventable contributing cause of the continuing HIV/AIDS epidemic and particularly its disproportionate impact on African-American and Hispanic communities.

Requested Action: **Direct the Attorney General to ensure that the Bureau of Prisons to encourages and cooperates with community organizations to provide voluntary, non-coercive, confidential and informed HIV testing, distribute sexual barrier protection devices (e.g. condoms) and to engage in HIV/STI counseling and prevention education in federal correctional facilities. Instruct the Attorney General to set outcome measures and programs that reduce the level of HIV infection and STIs among the federal prison population.**

Recommendation: The Attorney General should direct the Director of the Federal Bureau of Prisons to implement the above policy and prohibit federal correctional facilities from taking adverse action against a prisoner solely for possessing or using a sexual barrier protection device. Furthermore, the Bureau of Prisons should be directed to conduct a survey of all educational testing and other programs in federal and state correctional facilities for reducing the spread of STIs, and shall develop and request funding for a five-year strategy to reduce the prevalence and spread of STIs in such facilities. Agency guidelines should allow for the provision of HIV counseling and testing services by community-based service providers.

Process by which the Recommendation can be implemented: The Department of Justice Bureau of Prisons has authority and responsibility over federal correctional facilities and regularly conducts and publishes data from surveys of state and local correctional facilities as well. Though this recommendation reflects the thrust of H.R. 178: JUSTICE Act of 2007 introduced by Congresswoman Barbara Lee, the Attorney General and the Director of the Bureau of Prisons already have the authority to initiate the implementation of these recommendations.

Department of Justice
Bureau of Prisons

***Issue:* Provide comprehensive HIV prevention programming in correctional facilities**

<u>*Explanation*</u>: According to the U.S. Centers for Disease Control and Prevention (CDC), HIV prevalence is nearly five times higher among incarcerated populations than the general population. At the end of 2006, 1.6% of male inmates and 2.4% of female inmates in state and federal prisons were HIV-positive. Many of the activities that lead to incarceration for both men and women are the same activities that put them at risk for HIV (*e.g.*, injection drug use, sex work). Further, once incarcerated, inmates are more likely to engage in activities that create the potential for exposure to HIV, including unprotected sex, tattooing, body piercing, and injection drug use. In light of these facts, and that approximately 95% of inmates will ultimately return to the community, it is imperative that correctional facilities develop, adopt, and implement comprehensive HIV prevention programs to educate HIV-negative inmates about how not to be infected and to show HIV-positive inmates how to avoid transmitting the virus to others. A comprehensive program of this nature must necessarily involve *voluntary* HIV testing of all inmates with their informed consent, education about HIV and how it is transmitted, and distribution of sexual barrier devices.[3] One way to provide access to barrier devices is to allow community organizations to distribute condoms to inmates, along with information about their appropriate use and about sexually transmitted infections (including how to avoid them). There is ample evidence that condom use greatly decreases the risk of transmitting HIV and other sexually transmitted infections, and that distribution of condoms in correctional settings has not resulted in security problems. Evidence also shows that the more people are educated about the associated risks, the more likely they are to take precautions intended to reduce those risks.

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<u>*Requested Action*</u>: Attorney General/Department of Justice Issuance of Federal Bureau of Prison Regulations and/or Guidelines

<u>*Recommendation*</u>*:* The Administration should direct the Attorney General to issue guidelines and/or proposed regulations to ensure that inmates in federal prisons have ready access to comprehensive sexual health and HIV prevention services that include condom distribution. The Attorney General is authorized to prescribe regulations for the conduct of the Bureau of Prisons, part of the Department of Justice. *See* 5 U.S.C. § 301; *see also* 28 U.S.C. §§ 509 (regarding functions of the Attorney General), 510 (regarding delegation of authority of the Attorney General). The Bureau of Prisons is authorized, *inter alia*, to "manage infectious diseases in the confined environment of a correctional setting through a comprehensive approach which includes testing, appropriate treatment,

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[3] A CDC study in 2005 confirmed that HIV transmission occurs in prisons and recommended prison authorities consider making condoms available to inmates. *See* CDC, HIV Transmission Among Male Inmates in a State Prison System – Georgia, 1992-2005, MMWR 2006: 55: 421-426.

prevention, education, and infection control measures." 28 C.F.R. § 549.10;' *see also*, *e.g.*, 18 U.S.C. § 4042(a)(2) (Bureau of Prisons has responsibility for "the safekeeping, care, and subsistence of all persons charged with or convicted of offenses against the United States").

Section 2
Tab A

Community Letter

Top Priorities on HIV/AIDS for the Obama-Biden Administration From the Nation's Leading Advocates

The domestic HIV/AIDS epidemic is not over. Every 9 minutes someone in this country needlessly acquires HIV. In fact, more than one million Americans are living with HIV/AIDS. Half of these are not in medical care and one in five of them are unaware that they are even infected. Considering the magnitude of this problem, the neglect of the domestic epidemic over the past several years is all the more troubling and is evidenced by decreased financial resources, lack of leadership from the federal government, and the jettisoning of evidence-based standards in regard to prevention. The new annual incidence numbers released by the Centers for Disease Control and Prevention (CDC) earlier this year underscore the severity of the problem, revealing that our national epidemic is worse than previously thought. We must act and we must act now.

We are confident that the Obama-Biden Administration shares our concerns about the domestic epidemic. And while the Bush Administration has prioritized combating the epidemic overseas, we know you share the goal of bringing similar dedication and energy to tackling the epidemic here at home. The below represent the larger consensus among the nation's leading HIV/AIDS advocates of the top priorities.

► Develop and Implement a National AIDS Strategy

We call for the immediate development of a National AIDS Strategy (NAS) that is designed to lower HIV incidence, increase access to HIV care, reduce racial and ethnic disparities in the epidemic and integrate HIV with STD, viral hepatitis and TB programs at the local level. The NAS should rely on evidence-based policy and programming, set ambitious and credible targets for improved outcomes, ensure accountability at every level and require annual reporting on progress towards goals, address the social factors that increase vulnerability to infection, and engage multiple sectors in its development by focusing on the importance of public-private collaboration and ensuring equitable participation of those most affected by the disease including those living with HIV/AIDS, gay and bisexual men of all races, youth, people of color, women and injection drug users.

The NAS must create a coordinated federal response to preventing and treating HIV/AIDS that sets the stage for the development of cross-Departmental programmatic standards and outcome data that are based on scientific evidence, high quality and high accountability. Finally, sufficient financial resources must be prioritized to both develop and implement the NAS. To begin, the community supports the request of $1.4 million for the development of the NAS.

► Increase Funding for HIV/AIDS Prevention, Care and Treatment Programs Immediately

The development of a National AIDS Strategy will require thoughtful deliberation and time. However, because the domestic epidemic is at an emergency situation, funding in the areas of prevention, care and treatment must immediately be brought to realistic levels to deal with the epidemic. For Fiscal Year 2010, we call for:

- HIV Prevention and Surveillance at the CDC to be funded at least at $1.569 billion.
- Funding for the Division of Adolescent and School Health (DASH) at CDC of at least $66.6 million.
- Overall funding of the Ryan White HIV/AIDS Program, including the AIDS Drug Assistance Program, of at least $2.78 billion.
- Increased funding for the woefully neglected Minority AIDS Initiative (MAI) to a level of at least $610 million
- Overall increase to the National Institutes of Health budget for at least a level of $33.58 billion with a specific increase for HIV/AIDS Research to a level of at least $3.35 billion.
- Increase for the Housing Opportunities for Persons with AIDS Program to a least $470 million.

Additional information about the specific budgetary requests, including greater detail on how increases would be allocated in each program, can be found in the AIDS in America Transition Document at http://www.theaidsinstitute.org/downloads/AIDSinAmerica.pdf

► Restore Integrity to Our Nation's Prevention Agenda

Prevention initiatives have been increasingly politicized over the past several years. This has led to fear among prevention providers of doing innovative and targeted initiatives, a chilling of research on new interventions targeting highest risk communities, a severe shortage of financial resources from the federal government, and the trumping of ideology over science at nearly every turn.

Integrity must be restored to domestic prevention efforts. This must include: an end to all federal abstinence-only-until-marriage funding; implementing comprehensive sex education for all school-aged youth; an end to the war on condoms carried out by the previous Administration; a lifting of the federal ban on funding for syringe exchange programs; the appointment of diverse and qualified individuals to key HIV/AIDS advisory panels; and a scaling up of HIV prevention and education initiatives in federal prisons to include voluntary, non-coercive, confidential and informed HIV testing, HIV prevention education and the distribution of condoms.

Further, CDC, NIH, and other appropriate agencies must increase collaboration in confronting persistent challenges in rates of HIV incidence through a robust, comprehensive and strategic agenda of cross-cutting research aimed at identifying and mitigating the root causes and social determinants of HIV disparities such as employment access, housing, stigma and discrimination. In addition, they must aggressively explore new "combination" HIV prevention approaches that bridge biomedical methods, behavioral change, social and structural interventions. Finally, serious attention should be paid to the forthcoming National HIV/AIDS Elimination Act in the U.S. Congress and the principles it sets forth to end the epidemic.

► Meet the Health Care Needs of Those Living with HIV/AIDS

We call for the inclusion of HIV/AIDS care and treatment in the development of a plan to reform the U.S. health care financing and delivery system. This overall plan is something that must be launched within the first 100 days, but again, we recognize that additional time will be required to assemble and carry out such a plan and to include the many important perspectives of those affected by such a reform, particularly those living with HIV/AIDS.

Consequently, a number of steps must be taken to secure the needs of those living with HIV/AIDS as our country moves toward fixing a health care system in crisis. To this end, we call for a simple three year extension of the Ryan White HIV/AIDS Treatment Modernization Act. If no action is taken, this program will sunset at the end of Fiscal Year 2009. This cannot be allowed to occur.

Meeting the health care needs of those living with HIV/AIDS, though, will require additional steps. We call for the creation of a federal program to provide comprehensive health care services to persons living with HIV infection below 250 percent of federal poverty and who are not disabled by AIDS and therefore eligible for greater coverage under Medicaid. More immediately, this could be facilitated by the passage of the Early Treatment for HIV Act (ETHA) or otherwise enabling states to receive waivers under Medicaid to provide comprehensive care to this population.

► Eliminate All HIV-Specific Discrimination by Federal Agencies and Contractors

Government-sponsored discrimination reinforces stigma by putting the "official" seal of approval on unsound treatment of those with HIV/AIDS. Yet certain federal agencies --such as the Job Corp and the Peace Corps -- still exclude or discharge applicants and employees solely on the basis of their HIV status, despite the prohibition against disability-based discrimination in the Federal Rehabilitation Act of 1973.

The new Administration should promptly issue an Executive Order to direct that all federal agencies, contractors and subcontractors comply with federal disability antidiscrimination law in its treatment of HIV; and to bar them specifically from using HIV infection as a basis for a blanket exclusion of, or restrictions on, applicants, candidates, or employees. Further, the Department of Health and Human Services should quickly promulgate new regulations that eliminate the blanket exclusion of HIV-positive immigrants and visitors to the United States.

The Following Organizations Have Endorsed This Document

ACT-UP Philly
AIDS ACTION
AIDS Action Baltimore
AIDS Alabama
AIDS Alliance for Children, Youth & Families
AIDS Foundation of Chicago
AIDS Project Los Angeles
AIDS Taskforce of Greater Cleveland
AIDS Vaccine Advocacy Coalition (AVAC)
American Civil Liberties Union
American Public Health Association
American Social Health Association
Asian & Pacific Islander American Health Forum (APIAHF)
Association of Nurses in AIDS Care
Association of Nutrition Services Agencies, Washington DC
BIENESTAR
CAEAR coalition
Cascade AIDS Project
Catholics for Choice
Center for HIV Law and Policy
Community HIV/AIDS Mobilization Project (CHAMP)
Gay Men's Health Crisis (GMHC)
God's Love We Deliver
Harlem United Community AIDS Center, Inc
Harm Reduction Coalition
Health GAP, New York
HIV Health and Human Services Planning Council of New York
HIV Medicine Association
HIVictorious, Inc. - Madison, WI
Human Rights Campaign
Lambda Legal
Latino Commission on AIDS
Lifelong AIDS Alliance
National AIDS Fund
National Alliance of State and Territorial AIDS Directors
National Association of Social Workers
National Black Gay Men's Advocacy Coaltion
National Black Leadership Commission on AIDS, Inc.
National Coalition for LGBT Health
National Council of Jewish Women
National Minority AIDS Council
National Women and AIDS Collective
Ohio AIDS Coalition
Project Inform
San Francisco AIDS Foundation
Sexuality Information and Education Council of the United States (SIECUS)
Tennessee AIDS Care and Treatment Improvement Coalition, Inc.
The AIDS Institute
The Women's Collective
The Woodhull Freedom Foundation
TII CANN - Title II Community AIDS National Network
Treatment Action Group
Village Care of New York
Welcome House, Inc
Whitman-Walker Clinic, Washington, DC
Women Organized to Respond to Life-threatening Diseases (WORLD)

Section 2
Tab B

Transition Memo

until it's over
AIDS ACTION

memorandum

To:	Presidential Transition Team
From:	Rebecca Haag, AIDS Action Council
Re:	HIV/AIDS Priority Issues for Immediate Action
Date:	December 5, 2008

President-Elect Obama should continue to focus on the domestic HIV/AIDS issues that he has previously highlighted as part of his campaign plan, "Barack Obama and Joe Biden: Fighting HIV/AIDS Worldwide." This plan has widespread support throughout the HIV community and will allow him to announce plans towards achievement of his goals. In particular we recommend remaining focused on the creation and implementation of a National AIDS Strategy.

Additional immediate activities for the administration are organized below based on the categories in the campaign's plan and are followed by reference to the various HIV/AIDS transition documents that have been created (see Appendix for references). The campaign should specifically highlight the National AIDS Strategy along with some or all of these issues on World AIDS Day.

1. "Implement a National HIV/AIDS Strategy"
A. Within the first 100 days the President should appoint a panel of experts on HIV/AIDS and charge them to develop a National AIDS Strategy with targeted outcomes, measurable goals, timelines and accountability.
B. Call on Congress to approve $1.4 million in FY 2009 appropriations funding for the Office of National AIDS Policy to coordinate development of the National AIDS Strategy.
(Also supported in Democratic National Platform, NAS, AIA, CoC, NWAC, SAA documents, and directly supported by more than 350 local and national HIV/AIDS and other health organizations)

2. "Fix the Nation's Healthcare System"
Direct CMS to allow ADAP payments to count towards Medicare Part D True Out of Pocket (TrOOP) costs. Doing so will let people living with HIV who are eligible for Medicare Part D maintain their coverage and will help State AIDS Drug Assistance Programs to expand their drug formularies, end caps on programs and help thousands more people living with HIV to access life saving medications.
(Supported in the AIA, ADAP, CoC documents)

3. "Bring Medicaid Coverage to Low-Income, HIV-Positive Americans."
Call on Congress to pass the "Early Treatment for HIV Act" (ETHA) in the first year of his Administration. *(Supported in the Democratic National Platform, AIA documents)*

4. "Fight Disparities in Minority Communities"
A. Call on Congress to increase funding for the Minority AIDS Initiative by $20.1 million in FY2009.
B. Appoint People of Color, Women and Gay Men to the President's Advisory Commission on HIV/AIDS (PACHA) and the panel developing the National AIDS Strategy.
(Supported in the Democratic National Platform, CoC, NWAC, AIA documents)

5. "Improve Quality of Life for Those Living with HIV"
Call on Congress to Extend Ryan White CARE Act Program for three years.
(Supported in Democratic National Platform, AIA, CoC documents)

6. "Promote AIDS Prevention"
A. Call on Congress to discontinue funding for abstinence-only until marriage programs.
B. Direct the Department of Health and Human Services to require all programs that receive abstinence-only-until-marriage funding to provide written assurances they will not misrepresent or provide inaccurate information regarding the effectiveness and reliability of condoms.
C. Direct the Secretary of Health and Human Services to recertify that syringe exchange is an effective intervention for reducing the spread of infectious diseases such as HIV and does not increase drug use.
D. Call on Congress to remove the ban on the use of federal funding for syringe exchange from the Labor, Health and Human Services, Education and Related Agencies FY 2009 Appropriations bill. *(Supported in the AIA, CivRt, and CoC documents)*

6. "Assure Adequate and Safe Housing for Those Living With HIV"
A. Call on Congress to increase funding for the Housing Opportunities for Persons with AIDS (HOPWA) program by $15 million in FY2009.
B. Direct HRSA HIV/AIDS Bureau (HAB) to restore the rights of states and local communities to decide how long to fund transitional housing services for people under Ryan White. *(Supported in the AIA document)*

7. "Expand Funding for Research"
Call on Congress to increase funding for the National Institutes of Health by $1.65 billion in FY2009. *(Supported in the AIA document)*

8. "Reauthorize and Revise PEPFAR"
Call for the Secretary of HHS to rapidly develop regulations implementing the recent change in law that allows people living with HIV to enter the U.S. as visitors or immigrants.
(Supported in the AIA, CivRt documents. Note: Although this is a global HIV issues, it is strongly supported by domestic HIV/AIDS organizations.)

APPENDIX - Document Titles and Abbreviations:

There are 7 primary documents which reference domestic HIV/AIDS policy that are publicly available and of which we are aware. They are:

1. Framework for Developing an Effective National AIDS Strategy for the United States: October 2008 (referred to hereafter as "**NAS**")

2. AIDS in America: Recommendations for the First 100 Days of Office of the 44th President of the United States **(AIA)**

3. Fighting AIDS in Communities of Color an Action Agenda for the Next President (CoC)

4. National AIDS Strategy for Women in the United States: Submitted by the National Women and AIDS Collective - October 2008 **(NWAC)**

5. Critical Civil Rights Issues for People Living with HIV/AIDS in the United States: A To Do List for the New U.S. Administration's First 100 Days **(CivRt)**

6. The ADAP Coalition: Recommendations for the Next Administration and Congress Addition **(ADAP)**

7. The Stand Against AIDS - A Call from the Community for President Obama to Develop a National AIDS Strategy - November 2008 **(SAA)**

Section 2
Tab C

Framework for Developing an Effective National AIDS Strategy for the United States

Previously provided to the Presidential Transition Team

Section 2
Tab D

AIDS in America: Recommendations for the First 100 Days of Office of the 44th President of the United States

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Tab E

Fighting AIDS in Communities of Color an Action Agenda for the Next President

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National AIDS Strategy for Women in the United States: Submitted by the National Women and AIDS Collective – October 2008

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Critical Civil Rights Issues for People Living with HIV/AIDS in the United States: A To Do List for the New U.S. Administration's First 100 Days

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Tab H

The Stand Against AIDS: A Call from the Community for President Obama to Develop a National AIDS Strategy

Previously provided to the Presidential Transition Team

Section 2
Tab I

The ADAP Coalition: Recommendations for the Next Administration and Congress

Previously provided to the Presidential Transition Team

Section 2
Tab J

Advancing Reproductive Rights and Health in a New Administration

Previously provided to the Presidential Transition Team

Section 2
Tab K

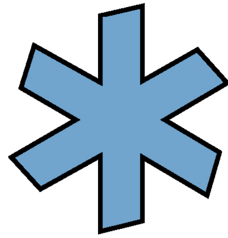
National Black Gay Men's Advocacy Coalition: HIV/AIDS Policy Recommendations for the Administration of President-Elect Barack Obama

Previously provided to the Presidential Transition Team

Section 2
Tab L

Guiding Principles for LGBT Inclusion in Healthcare Reform

Previously provided to the Presidential Transition Team



Guiding Principles for Lesbian, Gay, Bisexual and Transgender Inclusion in Healthcare Reform

As the Obama Administration begins to restructure the American healthcare system to insure that all Americans gain equitable access to the full continuum of health promotion, prevention and treatment services, we must also be able to effectively address the needs of distinct populations within the populace. For lesbian, gay, bisexual and transgender (LGBT) people, social stigma and systemic discrimination based on sexual orientation and gender identity have led to decades of lack of access to adequate, LGBT affirmative and culturally competent healthcare.

To eliminate health disparities in LGBT communities, healthcare reform *must* employ clear, guiding principals that are based on solid clinical standards integrated with a compassionate understanding of the healthcare issues facing this vulnerable population. In order to have effective and comprehensive healthcare reform, all legislative actions and governmental policy be inclusive of LGBT healthcare needs.

Healthcare disparities in the LGBT community have been recognized by numerous federal agencies and working groups, including the following divisions of the US Department of Health and Human Services (HHS): the Substance Abuse and Mental Health Administration (SAMHSA), Health Resource Service Agency (HRSA), Center For Disease Control and Prevention (CDC) and National Institute of Health (NIH). The HHS Secretary's Advisory Committee of Healthy People 2020 underscored the need to address LGBT health disparities and to give special recognition in the healthcare system to this population. Repeatedly, it has been published that being LGBT substantially impacts whether or not a person receives care and, when they do receive care, whether that care effectively speaks to all aspects of their lives.

Adding complexity to the clinical issues of LGBT health, are LGBT persons who are members of multiple communities facing health disparities. For example, LGBT people who lack insurance, may face other barriers of discrimination based on race, ethnicity, class or gender. They need access to healthcare services that are sensitive to and inclusive of all of their issues and concerns. Any panels, programs or systems set up to focus on communities facing health disparities must include LGBT concerns.

The following policy statements are provided for consideration in the development and full implementation of Healthcare Reform. The areas framed below are specific to the LGBT population, yet have application to heterosexual individuals, people of color, recent immigrants and nontraditional families; we believe these statements are critical for effective, comprehensive, compassionate, evidence based healthcare reform for the

LGBT Community. They are not listed in priority order, but are all important and many are dependent on each other.

- ***Cultural Competency Must Be Mandatory and Practical:*** The healthcare system must fully understand and embrace cultural competency for all people. Universal access to healthcare will have little meaning for many LGBT people if they do not have the ability to see culturally competent healthcare providers. Too often, LGBT people are misunderstood, mistreated or even discriminated against by healthcare providers. There must be systematic efforts to remove healthcare provider biases. The federal government must provide training, distribute best practices and awareness programs about LGBT people and their specific health needs. This is a necessary step for not only improving access, but also guaranteeing reliable, appropriate and culturally competent care.

- ***Guaranteed Access to Care*:**. An oversight body or some other decision making power must be instituted so that access to healthcare and specific services which are regulated by the federal government are not summarily removed by anti-LGBT administrations or officials. LGBT individuals, like all individuals, must have access to culturally competent healthcare and to health insurance that meets their needs. Lack of insurance causes all people to delay seeking medical attention and this delay typically forces people to forgo primary healthcare and be treated in emergency rooms instead. A lack of insurance prompts inadequate and deficient medical testing resulting in misdiagnoses. Furthermore, legal protections for LGBT people who disclose their sexual orientation and/or gender identity will lead to improved communication between provider and patients regarding sexual health, leading to improved care. This can lead to major progress toward more research on LGBT-specific health, increased awareness of existing LGBT health issues, and expanded prevention and educational programs (sexuality education in schools, for example).

- ***Clear Definitions in Policy and Legislation***: Regulatory, programmatic, policy and/or legislative definitions must be carefully crafted in order to increase access to healthcare in the LGBT community. For example, the terms family, parent and spouse often exclude LGBT families due to such families' lack of access to marriage rights. As long as the federal government's definition is exclusive of LGBT populations, same-sex partners who have entered into domestic partnerships and civil unions will not be able to access healthcare through programs designed to cover families, such as the State Children's Health Insurance Program (SCHIP). We encourage Congress, all agencies and any body overseeing healthcare reform to consider implementing the definition of family under existing federal sick leave regulations for federal employees, which reads:

  Family member means the following relatives of the employee:

  (1) Spouse, and parents thereof,
  (2) Children, including adopted children and spouses thereof;
  (3) Parents;
  (4) Brothers and sisters, and spouses thereof; and

(5) Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship.[i]

- ***No Exclusions on Pre-existing Diagnosis*****:** LGBT people are significantly more likely to have a pre-existing diagnosis. This is often due to reluctance of LGBT persons to access early diagnostic services for fear of anti-LGBT stigma or discrimination, which in turn leads to late treatment, and higher prevalence of disease. For many transgender people, their only entry point to care is through a diagnosis of Gender Identity Disorder. Gay and bisexual men have a significantly higher rate of HIV/AIDS and lesbians and bisexuals are significantly more likely to have cancer. All of these diagnoses can present substantial barriers to receiving insurance and healthcare.

- ***Healthcare Coverage for Transgender Inclusion Is Mandatory:*** Under the current healthcare system, insurance companies routinely refuse to insure and cover services for transgender individuals under the "transgender exclusion" clause. This allows insurance companies to deny coverage for any medical expenses related to transitioning.[ii] However, it would only cost a large-scale insurance program about $0.05 per insured to cover these transgender health benefits.[iii] Furthermore, insurance companies can neglect covering medical attention and procedures that are deemed necessary for the individual's sex assigned at birth (especially if it is inconsistent with one's gender identity). One instance is a female to male (FTM) transsexual who is registered as male with his insurance company should, if required, have coverage for his gynecological expenses as well. The exclusionary language of this clause is often unfairly expanded to include coverage for non-transgender related medical expenses.[iv] This must not be allowed to continue.

- ***Data Collection Tools Must Be Appropriate for All Populations to Facilitate Proper Planning, Clinical Care and Program Evaluation:*** There is an acute lack of information about the healthcare needs of LGBT people. Such a lack of information often results in a lack of appropriate services provided to LGBT people. Consequently, any nationally used forms must be inclusive of diverse sexual orientations and gender identities. For example, forms must include the ability to choose a same sex partner versus a spouse or to choose transgender under any demographic gender questions or for an individual to name parent 1 and parent 2 as opposed to mother and father.

- ***Adequate Assurances That Health Information Technology Will Assure Proper Clinical Information, Privacy and Address Changes for Transgender People:*** Heath information technology must have adequate safe guards in order to protect patients' privacy. For example, while in some health service settings, a person's sexual orientation and gender identity is relevant, in some situations it is not. Although sexual orientation and gender identity should be part of a person's routine medical history, unwilling and/or unprotected disclosure in medical

records could cause an LGBT person to be refused service or to receive substandard care. In addition, any standardized form of health information technology must allow transgender people a clear way in which to permanently change their gender marker and provide privacy for non gender matching health service needed that would publicly disclose confidential information, i.e. a transgender woman, living as a woman, who still is in need of a prostate exam by her primary care provider.

- ***Reproductive Healthcare Services Must Be Supportive for Conceptualization for All Patients:*** Any coverage of family planning services must allow for alternative methods of family creation. This can include invitro fertilization or surrogacy.

- ***The HIV/AIDS Epidemic Must Be Addressed:*** As noted above, gay men (especially gay men of color and youth), and transgender women are at increased risk for HIV/AIDS. For that reason the Administration should develop a National AIDS Strategy designed to lower HIV incidence, increase access to HIV care and reduce racial, ethnic, and economic disparities in the epidemic among LGBT populations. It should also integrate HIV prevention and treatment with STDs, viral hepatitis and TB programs wherever possible.

- ***Mental Health Parity Must Be Included*****:** As mentioned above, LGBT people are significantly more likely to suffer from mental health concerns or substance abuse. Any healthcare reform must have fully inclusive mental health coverage. Physical and mental health cannot be separated and should be covered at the same level.

Additional regarding information this policy statement may be obtained by contacting:

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[i] 5 C.F.R. sec. 630.201(b)

[ii] Marksamer, Jody, and Dylan Vade. "Recommendations for Transgender Health Care." Transgender Law Center. 9 July 2007. 9 July 2007 <http://www.transgenderlaw.org/resources/tlchealth.htm>.

[iii] Ibid.

[iv] Horton, Mary Ann. "The Cost of Transgender Health Benefits" Out and Equal Workplace Summit. 2008.