AAHIVM
AMERICAN ACADEMY OF HIV MEDICINE

AMERICAN ACADEMY
OF HIV MEDICINE

Public Policy PLATFORM

INTRODUCTION

The American Academy of HIV Medicine (AAHIVM) is an independent organization of HIV Specialists and HIV care providers dedicated to promoting excellence in HIV/AIDS care and to ensuring optimal care for those living with AIDS and HIV infection.

AAHIVM's constituency of HIV medical providers are on the front lines of the American response to the disease, both domestically and internationally. AAHIVM has a diverse membership composed of Infectious Diseases, Internal Medicine, Family Medicine, General Practice, Preventive Medicine physicians, Nurse Practitioners, Physician Assistants, as well as Dentists, and Pharmacists. AAHIVM Member distribution among these provider groups is proportionate to the specialty distribution of frontline providers nationwide.

Policy & Advocacy Efforts

As a professional trade association for HIV medical providers, developing public policy positions that accurately represent our membership is a demanding but crucial task. Our efforts are focused on the issues of greatest importance to our members, the patients they serve, and to the patients whom we hope to never have by preventing the spread of HIV.

There are many issues of concern to our members. As health care providers, and certified medical professionals, we seek policies that promote sound health practices, efficient medical care systems, and science-based public health policies. We also engage with issues that directly affect the care and well-being of people living with HIV/AIDS (PLWHA) or populations most vulnerable to the disease.

AAHIVM works at the federal level to affect legislation, regulatory decisions, and ongoing federal policy-making. This work is reflective of the positions of our members. AAHIVM works to educate the members of the Administration, Congress, regulatory agencies and other bodies on issues affecting HIV providers and their patients, and to advocate on behalf of our constituency.

AAHIVM regularly participates in strategic partnerships, coalitions, collaborations, and joint efforts with other national organizations that share common policy goals.

At the state level, AAHIVM works with our members in our state and regional chapters to advocate for changes in state and local health policies that affect the delivery of medical care to people living with HIV/AIDS (PLWHA). The AAHIVM Policy Department staff and Department of Member & Chapter Relations staff work with our members in states to define policy goals and to equip our members at the state level to effectively advocate for change.

AAHIVM Policy Platform
Purpose & Content

AAHIVM intends this Policy Platform to serve as a guide for its policy decisions, advocacy work, and organizational alliances. This document represents the values and interest of our members in public policy issues. The positions contained within this document are used to generate policy priorities, decisions, partnerships, advocacy work, and consensus statements.

The document contains two sections: The first section presents our guiding principles of our organization in all of our policy and advocacy efforts. These principles are broad in nature, yet they allow us to determine our support or opposition to issues based on a core set of guiding beliefs that our members hold as HIV care professionals. The second section focuses on policy statement and positions on specific policy topics of interest and priority to our members, or which the organization has addressed.

The sequence of principles and topics listed in this document, is not indicative of their priority level within our organization. The priority level of most policy issues changes regularly as the topics rise or fall in prominence on the national or local level. AAHIVM works to keep pace with the policy matters of the day, while striving to move forward on the issues of greatest concern to our members.

Our membership may not have a specific policy standpoint regarding certain policy issues or areas of interest. They may in fact have a diversity of opinions on a particular issue. Some highly charged issues lack universally agreement by medical providers. Some topics are constantly evolving in ways too nuanced for our members to agree on a mutual permanent position. In those cases, the Academy attempts to represent our membership's positions in their truest form. That may involve declining to engage a particular issue or representing the diversity of opinions that may exist among our members.

In all cases, this document attempts to clearly explain and identify the predominant values and opinions of our membership in policy issues.

The AAHIVM Policy Department & Policy Committee

The AAHIVM Public Policy Director and accompanying staff work on behalf of the members of the organization to represent their interests and positions on public policy issues.

The AAHIVM Policy Committee is a voluntary body of AAHIVM members dedicated to shaping the organization's positions on emerging policy issues. The Policy Committee is composed only of current members of the organization in good standing. The membership of the Policy Committee and the Policy Committee Chair are selected in accordance with the AAHIVM organizational by-laws.

The AAHIVM Public Policy Director works with the Policy Committee to hold regular meetings. The purpose of these meetings is to keep the committee informed of and active in the policy work of the Academy and emerging policy issues.

The AAHIVM Policy Committee advises the AAHIVM National Board on issues of importance to the organization and its members. It also makes recommendations to the National Board regarding the organization's positions, efforts, and priorities on these issues for their consideration and approval.

Policy Determination Process

The policy positions of the organization are determined by a vote of the AAHIVM National Board, on behalf of the membership of the organization.

The business of the AAHIVM Policy Committee is to consider issues of importance to the organization and its members as they arise, and to make recommendations to the National Board on the organization's policy positions, advocacy efforts, and issue priorities for their consideration and approval.

As policy issues arise that require consideration by the organization, they will be referred to the AAHIVM Policy Committee. The Policy Committee will determine whether the issue is appropriate for consideration by the committee, and by the organization as a whole, or whether it should tabled until another time.

If the Policy Committee chooses to consider the issue, then the committee will proceed to draw up a recommended position or statement on the issue. Once finalized by the Policy Committee, this position will be referred to the AAHIVM National Board for their approval. The National Board may opt to table a recommendation, or to return the policy recommendation back to the Policy Committee for reconsideration or revision.

Once the AAHIVM National Board approves a position, it will be considered the official position of the organization on an issue.

The AAHIVM Public Policy Director and organizational staff will use the official positions of the organization to conduct ongoing policy and advocacy work of the organization while also keeping the Policy Committee and National Board informed of said activities.

Special Circumstances

At times, a determination or response to a particular issue is needed within a short timeframe making it impractical to wait until the next meeting of the full Policy Committee or National Board.

In this case, the Policy Director and the Chair of the Policy Committee may work in conjunction to develop a response within the necessary timeframe. This effort may also be referred to the AAHIVM Executive Committee for their guidance, determination or approval in lieu of the full National Board.

Once the Executive Committee approves a decision, it will be treated as final until the next National Board meeting. In this case, the Policy Committee and Board should be informed of the deliberations and determinations of the Policy Director, the Policy Committee Chair, and the AAHIVM Executive Committee, and have the opportunity for review at the next National Board meeting. At such time, it can be voted upon by the National Board, according to the normal procedure.

All effort should be made to ensure participation of the Policy Committee and National Board, according to normal procedure, if circumstances allow.

The AAHIVM Institute for Hepatitis C

In 2015, AAHIVM launched a new effort to improve care for patients with hepatitis C (HCV) infection, "The Institute for Hepatitis C." According to the CDC at least 25% of Americans with HIV/AIDS are co-infected with the hepatitis C virus (HCV). As highly active antiretroviral therapy has allowed PLWHA to reach near-normal life spans, end-stage liver disease related complications secondary to HCV have become the leading cause of death among those living with HIV/HCV co-infection. The dramatic strides in HCV research reached fruition in 2014 with FDA approval of new HCV regimens comprised of all oral direct-acting antivirals (DAAs), offering the possibility of a HCV cure in over 90% of co-infected patients usually with a 12-24 week course of well-tolerated all oral therapy. Many patients are being denied access to these life-saving advances as many payers are restricting access to those at the most advanced levels of disease for cost-containment reasons.

As such the work of the Institute includes not only informing and educating providers on the rapidly changing field of HCV medicine, but also keeping them up to date on policy issues related to HCV and advocating whenever possible for improved access to screening for HCV and availability of the new well-tolerated, curative all oral HCV treatment options for all co-infected persons.

The policy and advocacy work of the Institute is not separate from the process, functions, or positions of AAHIVM as an organization. Rather it is an increased facet of our work.

As such, all policy advocacy work for the Institute, and positions taken with its name, are beholden to the same processes and procedures as all of the policy and advocacy work of AAHIVM.

The roles of the AAHIVM Public Policy committee and the National Board will also be the same for the Institute.

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POLICY **PRINCIPLES**

This section contains statement reflecting the principles of the organization and its members in the area of public policy.

RECOGNITION OF HIV CARE AS A MEDICAL SPECIALTY

The American Academy of HIV Medicine (AAHIVM) and its members support the recognition of HIV care as an area of medical specialty and encourage all providers serving HIV-infected patients to seek appropriate training and certification in this field.

HIV medicine is a complex and involved field of medical care. Advances in care and treatment are ongoing and place significant demands on HIV providers to stay abreast of the current HIV diagnostics and treatments.

The evolution of HIV care has transformed the practice of HIV medicine such that it now often requires a hybrid of HIV expertise and depth and breadth of primary care skills to address the co-morbidities that people living with HIV/AIDS (PLWHA) develop as they live for decades with the disease.

A large body of evidence indicates that the two best predictors of high-quality, cost-effective HIV care are patient management experience and ongoing professional development through HIV-related continuing medical education, or certifications.

AAHIVM supports the credentialing certifications of the organization as a demonstration of expertise in HIV medicine.

AAHIVM's HIV Specialist™ (AAHIVS) and HIV Expert™ (AAHIVE) certifications are the first and only credentials offered domestically and internationally to physicians (MDs and DOs), nurse practitioners, and physician assistants specializing in expert level HIV care.

In addition, AAHIVM also offers the HIV Pharmacist™ (AAHIVP) credential to HIV-specialized pharmacists. The acquisition of the Academy's credentials indicates an up-to-date core knowledge and proficiency in HIV diagnosis and treatment to patients, colleagues, employers, governments and third-party payers. It offers appropriate recognition of the highly technical sub-specialty that is HIV medicine.

AAHIVM supports legislation and policies that promote recognition of HIV specialty care that is codified in all state and federal coverage and care programs.

Several states have acknowledged and codified the recognition of specialization in HIV care and acknowledge AAHIVM's certifications. Currently, New York,[1] California,[2] and Maryland[3] have state laws that recognize HIV Medicine as a specialty and require certification to that effect.

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[1] New York law requires that managed care organizations provide treatment for those on HIV Special Needs Plans (SNPs) by HIV specialists. An HIV Specialist is defined by committee. The New York definition was last revised in December of 2004 and has both an experience and an education component, the latter of which may be filled by AAHIVM accreditation

[2] In 2001, California amended its definition of HIV Specialist to specify those who have been accredited by a government agency or independent organization. Previously, California had required that health insurers guarantee access to HIV specialists, but its definition of an HIV specialist was not concrete.

[3] Maryland, in its administrative code, requires that health insurers cover treatment by HIV/AIDS specialists. An HIV Specialist must either have an ABMS certification in infectious diseases, or have performed a minimum amount of HIV care and completed an HIV education requirement, which can be filled by passing the AAHIVM credentialing exam. These requirements were recommended in September 2003 and took effect January 4, 2004.

ACCESS TO CARE FOR ALL PEOPLE LIVING WITH HIV/AIDS

The American Academy of HIV Medicine (AAHIVM) and its members believe that all people living with HIV/AIDS (PLWHA) should have access to high-quality appropriate medical care and treatment.

Historically, access to care has been a significant issue for PLWHA, leaving many uninsured, under-insured, and marginalized from the health care system. As a whole, HIV-infected patients are appropriately classified as a medically underserved and vulnerable population.

In addition, data indicates that HIV disproportionately affects the most vulnerable in our society—those who have less access to prevention and treatment services and, as a result, often have poorer health outcomes. Studies have shown that HIV highly impacts certain patient groups including racial and ethnic minorities, youth, men who have sex with men, gay and bi-sexual populations, and transgender individuals.

AAHIVM supports policies that increase access to medical care for all PLWHA.

We oppose policies and practices that limit access to care for, or discriminate against PLWHA, and those at risk for HIV infection.

AAHIVM supports policies that provide affordable and stable access to the full range of health care services which contribute to effective management of HIV disease and co-occurring conditions. We oppose payer and coverage practices that create barriers to accessing vital medical care, including, prior-authorization requirements for HIV care services and medications, and arbitrary service limits.

We support policies that promote access to a wide range of medical provider types and specialties.

AAHIVM has a diverse membership composed of Infectious Diseases, Internal Medicine, Family Medicine, Preventive Medicine, and General Practice physicians, Nurse Practitioners, and Physician Assistants, as well as Dentists, and Pharmacists. Since the beginning of the HIV/AIDS epidemic, medical providers from a diversity of specialties have led the medical response to this disease, including Internal Medicine, Family medicine, Primary care, Oncology, and Obstetrics-Gynecology. A large body of evidence indicates that the two best predictors of high-quality, cost-effective HIV care are patient management experience and ongoing professional development through HIV-related continuing medical education and/or certifications.

We oppose payer and coverage practices that create barriers to HIV/AIDS patients accessing services from qualified medical professionals, including limited provider networks, and prior-authorization or utilization management restrictions targeting certain types of providers for services and prescriptions.

We support policies that reduce financial barriers to care and increase affordable care for all PLWHA.

Financial cost of care can be one of the largest barriers to access to medical and care services. We oppose policies that create undue financial burden on PLWHA including, caps on coverage, burdensome cost sharing requirements, and premium rate-setting according to health status, gender, age or other demographic factors.

We support policies that increase patient linkage to care following HIV testing.

It is vitally important that patients who have received an HIV diagnosis following HIV testing be expeditiously linked to long-term medical care systems. Data shows that early initiation of HIV treatment is the largest predictor of long term health for an HIV patient. Successful HIV treatment relies on early intervention and consistent retention in medical care. Too often following an HIV diagnosis, patients are not properly connected to and retained in adequate health care systems, which can be deleterious to their immediate health and long-term disease prognosis. Even those who receive HIV testing, and are not infected but have high risk factors for contracting the virus would benefit from linkage to regular medical care and prevention services. Linkage to care following HIV testing is a vitally important component of successful testing initiatives.

We support policies which promote patient retention in care.

Retention in care is an important predictor of long-term success in managing HIV infection. Any public health and industry/commercial policies that result in disruptions to patient access to care can have profoundly negative impact in patient health outcomes. Therefore, we oppose any such policies and payer and coverage practices which lead to disruptions in patient access to care, including sudden changes to provider networks, limitations on certain types of prescribers, and changes or cancellations in programs, coverage, and benefits.

ACCESS TO TREATMENT FOR ALL PEOPLE LIVING WITH HIV/AIDS

The American Academy of HIV Medicine (AAHIVM) and its members support policies that ensure patients have access to the life-saving medications that are necessary for the treatment of their disease and for their overall health and wellness.

Since AIDS was first reported in 1981, nearly 40 medicines have been approved to treat HIV infection in the United States. The introduction of Highly Active Anti-Retroviral Therapy (HAART), brought about a revolution in the care of HIV patients, and changed an HIV diagnosis from an acute fatal illness into a manageable yet complex medical condition. Further innovations in HIV treatment have led to more tolerable drugs with fewer side effects, and also the introduction of combination therapies which greatly decrease the burden of treatments on patients and promote increased adherence.

AAHIVM supports access to treatment that is optimal for each individual patient's needs, and supports provider determination of the best course of treatment.

Today, HIV drug therapy typically involves the prescription of complicated combinations of medications from several therapeutic classes. Successful antiretroviral treatment requires close monitoring for effectiveness, strict adherence by patients, and evaluation and mitigation of side effects by a medical professional. Individual response to treatment is not always equal. The optimal treatment for one person may not be the same for another. Specific patient indicators of drug resistance, patient nutrition, mental illness, substance abuse, co-morbid conditions and tolerability inform provider decisions about which treatment regimen is best for each patient.

In addition, many PLWHA suffer from co-occurring conditions which require concurrent medical treatment, patient interventions and detailed coordination of medications. Disruptions in treatment of the other medical conditions in an HIV patient can lead to medical complications, hospitalizations, higher treatments costs, and worse health outcomes.

We believe that the best determination of appropriate medical treatment occurs in the relationship between provider and patient. We support policies that promote provider determination of optimal course of treatment based on clinical evidence, indicators for individual patients' outcomes in terms of age, gender, race, and ethnicity, and considerations of safety, efficacy and tolerability of particular drugs.

We oppose policies that restrict provider determination of treatment, or access to the optimal medication selection for a patient, including prior authorization requirements, caps on pharmacy benefits, restrictive formularies or tiering practices, and restrictions on the prescribing of HIV and related therapies to only certain types of providers or specialties.

AAHIVM supports policies that facilitate patient adherence to treatment regimens.

In order for an HIV patient to reap the benefits of these life-saving medications, they must maintain at least 95% adherence rates over a lifetime. Missing as few as two doses in a month can lead to development of viral resistance to medication. Disruptions in access to treatment can have life-threatening consequences to individuals living with HIV. The medical management of these patients is complex and best left to the providers involved in their care.

Therefore, we oppose policies that could lead to disruptions in patient adherence to medication regimens, including prior authorization requirements, caps in pharmacy benefits, restrictive formularies, and restrictions to prescribing by certain types of providers or specialties.

We also oppose forced participation in mail-order pharmacies for HIV-infected patients.

Mail order pharmacies can, in some cases, create problems for patients in terms of access to medications, patient adherence, and patient privacy due to a wide variety of factors.

Some patients prefer in-person interaction with a Pharmacist and pharmacy staff for a variety of services that contribute positively to their overall health and well-being, adherence to medications, and retention in care. Some patients receive adherence counseling, and a variety of other beneficial services, such as initial screening for and diagnosis of tolerability issues from their Pharmacist. Requirements by payers to use a mail-order pharmacy service may prove disruptive to care and treatment for those patients.

HIV-infected patients are often encouraged by their provider fill two or three months of prescription at a time in order to ensure they will not run out of their medications. Mail order pharmacies often create restrictions on these types of practices, which have been shown to have benefit for some patients in terms of adherence.

Additionally, mail order pharmacies can potentially create the possibility of disclosure of patient medical information that should be protected under HIPAA. This can also be a concern in any pharmacy situation, and all pharmacies must ensure that patient privacy is protected under all circumstances.

Mail-order pharmacies may be preferable to some patients. However, patients should have the choice to opt-out and obtain services from a local pharmacist if they prefer.

While mail-order pharmacies may offer some cost-savings for payers, access to medications, patient adherence, and patient privacy are too important for HIV-infected patients to be required to use these delivery methods.

AAHIVM supports policies that maximize so-called "treatment as prevention" opportunities for individuals as well as for the public health.

In recent years, scientific studies have demonstrated that effective HIV treatment leads to viral suppression and also reduced risk of transmission of HIV. Effective HIV treatment can also act as a method of prevention. Further, scientific models have indicated that widespread HIV treatment in a population may reduce transmission across the full population. In addition, uninterrupted access to optimal antiretroviral therapy will prevent the development and transmission of drug resistant virus in the community.

We oppose practices that limit access to HIV treatments and medications for common co-occurring conditions for the sake of cost-containment efforts by payers and coverage programs.

While we are sensitive to the challenges faced by policy makers, and the financial burdens on coverage entities, programs and payers, the access of PLWHA to life-saving medications is of utmost concern to HIV providers. We oppose any restriction of needed and optimal therapies for HIV patients for the reason of budgetary restrictions and cost savings to payers.

We generally oppose attempts to create savings in drug treatment costs that are to the detriment of the health of individuals infected with HIV.

These policies are short-sighted in considering short-term budgetary consideration while failing to account for the long term savings available through optimizing health outcomes and wellness of individuals, lowered hospitalization rates and disability costs, as well as reduced rates of infection across an entire population.

Historically, patients with complex drug treatment needs have been protected from such policies. The Medicare Part D program, for example, has declared 6 classes of such drugs, including antiretrovirals and immunosuppressants as "protected classes." In doing so, the federal government has acknowledged the value in protecting the health of these vulnerable patient populations from budgetary restriction efforts, and created a permanent policy of protection around them.

Therefore, we oppose policies that restrict access to ARVs and medications for common co-occurring conditions such as formulary lists, prior-authorization restrictions, utilization management restrictions, and coverage limitations.

We also oppose formulary design and coverage policies which require providers to prescribe less-efficacious drugs, or drug formulations that are not in the best interest of the patient.

REDUCTION OF HEALTHCARE DISPARITIES

The American Academy of HIV Medicine (AAHIVM) and its members support policies that work toward elimination of disparities in accessing coverage and quality medical care due to socio-economic status, prior medical condition, race, ethnicity, gender, sexual orientation, gender identity, actual or perceived disability, age, primary language, and geography (state of residence and type of community – urban or rural).

While anyone can become infected with HIV, some American demographic groups are historically more highly impacted than others. This includes gay and bisexual men of all races and ethnicities, transgender individuals, black men and women, Hispanics/Latinos, and injection drug users.

There are also epidemiological areas of impact in certain geographic areas, including large urban areas and cities, the Southern states, Puerto Rico and the U.S. Virgin Islands.

AAHIVM supports policies that encourage all providers to deliver culturally-sensitive and competent care.

Education in current standards of care and cultural competency training for underserved populations should be made available for all HIV providers.

Lack of access to culturally appropriate care and prevention resources, along with homophobia, stigma, and substance abuse are key drivers of the epidemic among LGBT populations, including MSMs and transgender individuals. We encourage multi-faceted efforts to ensure culturally sensitive care for lesbian, gay, bisexual and transgender persons living with HIV. Culturally sensitive care should be a standard for all who treat HIV disease and interact with these patient groups.

AAHIVM supports provision of culturally competent and sensitive medical care for racial and ethnic minorities. In addition, we support creation of culturally and linguistically appropriate materials and services for individuals with language barriers.

AAHIVM supports policies to reduce stigma among impacted populations and promote awareness.

Efforts should focus on populations that are often stigmatized, due to historically high rates of infection. A 2010 report from the Centers for Disease Control and Prevention (CDC) shows that nearly one in five MSM in major U.S. cities is living with HIV and nearly half of these are unaware of their status. This analysis also showed that the majority of them are youth and men of color.

AAHIVM supports initiatives to close the differential gap in the preventive interventions, medical care and effectiveness for some ethnic or social populations.

For example, one goal should be to close the differential in access to antiretroviral medications for communities of color which have less access to medical interventions, less favorable outcomes, and increased rates of HIV transmission.

AAHIVM supports policies to prioritize medical workforce diversity as part of efforts to address the shortages in the primary care workforce and HIV medical workforce.

The dearth of minority medical providers is particularly pertinent to the HIV medical community because of the disproportionate impact that HIV disease has had on African American and Latino/Hispanic populations. HIV clinics and programs find it particularly challenging to recruit medical providers that mirror their African American and Latino/Hispanic patient populations and to recruit Spanish-speaking clinicians and staff. Special attention should be paid to areas of medicine, such as HIV disease, where minority populations are heavily represented.

We encourage the cultivation of greater minority representation among qualified HIV providers, including such programs as the Health Professions Title VII and VIII programs. A laudable goal would be to increase the number of minority providers to more closely reflect the patient population they serve.

SCIENCE AS A BASIS FOR HEALTH POLICY

AAHIVM supports approaches to public policy and policy making efforts that are based on current scientific understanding, best medical practices, and evidence-based research.

As medical professionals, our members support scientific research and knowledge as the basis for policy making in the public arena. We believe that public health policies, public policy, and criminal statutes should take into account the most up-to-date scientific information about disease transmission, prevention, and medical interventions. We support reference to medical "best practices" and peer-reviewed recommendations as an excellent starting point for developing policy.

We believe that public policies, and laws around disease transmission should be evidence-based and non-discriminatory in nature. They should serve public health goals and promote public awareness.

As front-line responders, we identify keenly with the interest of government officials and elected leaders to protect the public's health and combat the spread of disease. As HIV providers, we are very aware of how easily stigma against patients can be created. We urge public policies to focus on demonstrated best practices that work to facilitate real progress in combatting the spread of disease, while having appropriate protections for individual privacy, rights, and freedoms.

AAHIVM supports policies that respond to HIV disease exposure, transmission, and infection in the same way as other communicable diseases.

When HIV/AIDS first appeared, a degree of public hysteria occurred surrounding the disease. In the wake of this, many ill-conceived and ineffective laws were passed targeting the disease and those infected with it. Although scientific and medical knowledge of HIV/AIDS has greatly advanced, many of these policies have not, leading to laws and policies that are unnecessary, stigmatizing, harmful and unfair, and in some cases should be changed (eg. written consent for testing).

Our members oppose public policies and laws that distinguish HIV disease from other comparable diseases. We believe public health policy on HIV should be comparable to that of other sexually transmitted or communicable diseases such as tuberculosis, hepatitis, herpes, or syphilis.

We believe that policies on HIV should take into account the high levels of stigma and prejudice associated with disease transmission and seek to protect individual privacy, rights, and freedom.

We urge lawmakers, when considering public health policies aimed at combatting the spread of disease, to seek the opinions of top scientists and HIV medical providers, and base their efforts on science and best practices.

AAHIVM and its members recommend that policies within private health coverage programs, and public health payers, be based on care and treatment guidelines and recommendations set by medical agencies and scientific bodies, and the latest scientific information.

Too often, decisions about patient care are restricted by policies set by health coverage programs and payers instead of the treating medical provider in consultation with the patient.

These policies often fail to take into account medical best practices, or treatment recommendations from medical or scientific bodies and/or health agencies. Sometimes, coverage determinations are set arbitrarily, with no justification based in medical science. We urge payers to refer to the most current medical treatment guidelines set by medical agencies (DHHS, CDC, etc.) as a starting point for coverage determinations and formulary polices.

Of even more concern, some patient benefit and coverage policies are set for no other reason than to save money on patient care.

While we are sensitive to the pressures faced by policy makers, and the financial burdens on coverage entities, programs and payers, the well-being of HIV patients is of utmost concern to HIV providers.

Best practice recommendations, and clinical practice guidelines set by medical agencies (DHHS, CDC, etc.) and scientific bodies (USPHS, IDSA, etc.) should serve as standards of medical care for PLWHA. They should serve as a basis for coverage policies focused on patient care and treatment.

PROVIDER DETERMINATION OF CARE

As a general principle, AAHIVM supports the ability of providers to determine the best course of treatment for the patients under their care, within the confines of the law and medical licensure standards.

As an organization of front-line HIV medical providers, we support the ability of clinicians to determine the best course of treatment for their patients. We believe that the best determination of appropriate medical treatment occurs within the relationship between provider and patient, taking into account the evidence-based treatment guidelines and available clinical data.

HIV infection responds to particular treatment regimens in different ways in patients so that the optimal treatment for one person may not be the same as for another. The key person with the training and knowledge required to make that determination is the treating medical provider.

Successful HIV drug therapy involves the prescription of complicated combinations of drug therapies, close monitoring for effectiveness, rigid adherence by patients, and evaluation and mitigation of side effects by a medical professional.

Individual response to antiretroviral treatment is not always equal. Specific patient indicators of drug resistance heavily inform provider decisions about which treatment course is best for each patient. Decisions about care should be based upon best practices in care, clinical practice guidelines, and clinical evidence indicating varied outcomes for individual patients in terms of age, gender, race, and ethnicity, considerations of safety, efficacy and tolerability of particular drugs.

Treating the medical needs of HIV-infected patients with a “one size fits all” approach can lead to unnecessary medical complications and lesser health outcomes.

In recent years in the field of health care, initiatives to improve the health system or increase cost efficiency of care programs, have led to restrictions being placed on patient insurance benefits that restrict the ability of providers to prescribe optimal drug regimens for patients.

We are concerned with policies or determinations that limit access to vital medications such as antiretrovirals, immunosuppressants, anti-depressants and others. Requirement of prior authorization for prescription of drugs creates an administrative barrier that restrict the ability of providers to prescribe the best course of medication for each individual patient. It can also give the impression that one medication or class of medications is more efficacious than another, whether that is in fact, supported by actual scientific or clinical evidence.

AAHIVM supports policies that take into consideration the highly individualized needs of HIV infected patients, and empower providers to give the best possible care to their patients, including Prescriber Prevails policies.

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POSITION **STATEMENTS**

This section contains position statements on specific policy issues, subjects, or questions.

AMERICAN ACADEMY OF HIV MEDICINE

Policy Position Statement

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HIV MEDICAL PROVIDER REPRESENTATION ON GOVERNING BODIES

The American Academy of HIV Medicine (AAHIVM) and its members believe that government bodies responsible for HIV policy-making should include medical provider representation, preferably from an HIV Specialist.

It is our opinion that any conversation about HIV/AIDS in the United States must start with a conversation about appropriate medical care for the infected. Policy decisions about HIV as a disease, such as health care access, prevention, research, and health education, are inextricably intertwined with the practice of HIV medical care.

It is our belief that federal and state level government committees, task forces, panels, and other governing bodies that would take on policy work concerning HIV policy and related subjects should include direct input from HIV providers. This would include medical providers who have demonstrated experience in care for HIV patients and also advanced training in HIV medicine and related topics. As an organization, we work to nominate and support inclusion of HIV medical care providers generally, and our members specifically, in these key positions.

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Policy Position Statement

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THE HIV MEDICAL WORKFORCE

The American Academy of HIV Medicine (AAHIVM) and its members believe that the HIV workforce should be expanded and support strategies to draw new providers into the HIV care field and provide support to those HIV providers currently in the workforce.

The U.S. HIV care system is facing a crisis in care capacity. Data from a 2008 survey conducted by AAHIVM shows that more than 32 percent of current HIV clinicians will stop providing care over the next 10 years, and there are inadequate numbers of new providers to replace them.

Shoring up the pipeline of qualified HIV medical providers is an extended process that requires years of targeted interventions. AAHIVM supports polices that provide for assurance of a well-trained HIV workforce.

We support strategies to increase the number of HIV medical providers, including health professions training grants, tuition reimbursement, student loan repayment, and other financial incentives to draw new providers into HIV care management. We see the National Health Service Corps Scholarship and Loan Repayment Programs as excellent examples of this.

We also support strategies aimed at medical education, including rotations in HIV care and/or exposure to populations impacted by HIV for medical students, clinical fellowships, HIV training for all providers in the course of their medical education, clinical training opportunities, satellite learning, and web-based programs. We support innovations within medical residencies, such as an “Area of Concentration” (AOC) in HIV/AIDS medicine within Family Medicine, Internal Medicine, and Preventive Medicine residency programs.

It is also important to encourage more primary care providers, and non-physician providers, to obtain HIV medicine training, especially in areas with high rates of infection.

REIMBURSEMENT AND PAYMENT

The American Academy of HIV Medicine (AAHIVM) and its members support reimbursement policies by all payers that reflect the true cost of medical care.

We believe that appropriate reimbursement for HIV care is vital to ensuring proper patient care by guaranteeing provider ability to maintain services.

In a 2008 AAHIVM survey of Ryan White Part C-funded clinics, the clinicians reported reimbursement as being one of the biggest challenges to recruiting HIV clinicians.

Most HIV medical providers receive reimbursement-based funding from a mix of federal and state government programs such as Ryan White, Medicare, Medicaid, and private insurance payers.

A majority of HIV patients rely on Medicaid for their health coverage. Under the current reimbursement levels, many HIV clinics operate at annual deficits that are growing and leading to cuts in services, staff and clinic hours. Addressing medical provider reimbursement issues for primary care providers and other specialists that practice HIV medicine under Medicaid and Medicare is critical to sustaining the HIV care system.

Reimbursement from all payers should reflect the true cost of evaluation and management, medical procedures, labs, and in-office treatments. Access to expert HIV care depends on fair payment mechanisms that cover the cost of delivering HIV primary and associated care as provided by primary care practitioners and other specialists. Reimbursement rates should, at a minimum, allow both clinics and providers the ability to maintain the standard of care for their patients.

AAHIVM supports policies that encourage the delivery of high-value care models, without sacrificing individual patient care.

We support value-based payments rather than fee-for-service payments to insure high-quality and cost-effective care to our HIV-infected patients. Reimbursement for evaluation and management services (E&M) for HIV-infected patients should be balanced appropriately in comparison to reimbursement for procedure-based specialties.

Payment mechanisms should support effective models for delivering high-quality coordinated care to HIV-infected patients, such as the “Primary Care Medical Home” (PCMH).

We support enhanced reimbursement for programs that contribute to high-quality HIV medical care, such as behavioral health services, and provide sufficient resources to support quality improvement and the adoption of health information technology by HIV care providers.

AAHIVM supports enhanced reimbursement rates for HIV Specialists, similar to other medical specialties.

Studies show that HIV care delivered by experienced HIV providers yields better patient outcomes that result in cost savings to the health care system.

Because HIV care is complex and demanding, credentialed HIV specialists should be reimbursed at rates comparable to other medical specialists. Reimbursement policies must be reformed to recognize the value and importance of primary care and other medical specialties and types of providers that practice HIV medicine.

AAHIVM supports reimbursement policies which actively encourage recruitment of new HIV providers into the field, and increase the HIV workforce.

Data indicates that clinical practices are struggling to recruit new HIV providers. Furthermore, many HIV providers who first entered the field in the early days of the epidemic expect to retire in the next 10 years, according to a 2008 survey of AAHIVM members[4].

Funding challenges must not be allowed to dissuade consideration of HIV medicine as a potential career choice for newly trained clinicians.

[4] Carmichael, J. Kevin, et. al., 2009, "Averting a Crisis in HIV Care: A Joint Statement of the American Academy of HIV Medicine (AAHIVM) and the HIV Medicine Association (HIVMA) On the HIV Medical Workforce"

COORDINATION OF FEDERAL PROGRAMS AND PROVIDER REQUIREMENTS

AAHIVM and its members encourage increased coordination between HIV/AIDS programs across the Federal government and also between federal agencies and state, territorial, tribal, and local governments.

HIV/AIDS programs are a loosely linked web of resources and responsibilities, ranging across multiple federal agencies, including Health and Human Services (HHS), Housing and Urban Development (HUD), Justice, Veterans Affairs (VA), USAID and Department of Defense. Within HHS, responsibility for HIV programs is spread across multiple agencies including the Centers for Medicare & Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office of HIV/AIDS Policy, the Office of Minority Health, and others.

There is a distinct lack of efficient coordination across federal health care programs that provide care and treatment for HIV. Overlapping and competing programs can be quite burdensome for providers and their patients to navigate.

There is a significant need for better collaboration, integration of services, and decreased redundancy across these different programs.

AAHIVM and its members support efforts to reduce the application and reporting burden on HIV providers who participate in federal HIV/AIDS programs.

Development of common data collection and reporting systems across all programs and settings would better facilitate and enable monitoring of clinical care utilization, quality indicators, and health outcomes for people living with HIV.

HIV providers often receive funding from multiple sources with different grant application processes and funding schedules, all with varied reporting requirements. The administrative and data reporting requirements under federal programs, such as Ryan White and Medicare Part D, have grown exponentially, while fiscal resources to support these requirements have decreased.

The requirements are contributing to the cost of HIV care and draining valuable HIV medical provider resources. These administrative burdens reduce the medical provider's time to provide direct care while also reducing overall job satisfaction. They may even serve to discourage clinicians from choosing to practice HIV medicine.

There is a need for streamlined reporting requirements across all federal health programs, and also for coordination of application periods for grant-based programs.

INTERDISCIPLINARY / MULTI-DISPLINARY CARE, AND COORDINATIVE CARE

The American Academy of HIV Medicine (AAHIVM) and its members support policies that foster better coordination of care across various medical specialties and the collaboration of specialists across medical fields in order to promote better patient care and outcomes for HIV patients.

We support an interdisciplinary approach to the treatment of HIV-infected patients as a way to promote efficient high-quality care delivery.

The evolution of HIV care also has transformed such that it now often requires a hybrid of HIV expertise, primary care, and other specialties. Serious co-morbidities such as hepatitis C, lipid disorders, mental health disorders and cancers are common among people with HIV and often require co-management with or referral to other specialists. HIV patient care also benefits from coordination with dental care and addiction services.

Cooperative care and coordination-of-care efforts are necessary to address the co-morbidities that people with HIV develop as they live for decades with their disease.

We support the promotion of the "Medical Home" model as defined by HRSA and AHRQ, and other multidisciplinary approaches to HIV care.

Many different models for managing the care of patients with HIV have evolved to ensure patients have access to quality HIV care. Lessons on effective management of chronic conditions across specialties such as through medical homes must be applied to HIV disease.

Under one model, HIV clinics serve as "Medical Homes" with the HIV medical provider serving as the HIV specialist and primary care provider.

We support policies to increase referrals to experienced HIV specialists, without creating limitations on patient access to care.

HIV care that is delivered by experienced HIV medical providers has been proven to lead to better outcomes for HIV-infected patients and ultimately result in cost-savings to the health care system.

However, trends in medical coverage indicate that an increasing number of patients will be overseen by a primary care provider in the future. We support and encourage less-experienced medical care providers, and those who are not credentialed HIV Specialists, to collaborate with HIV-specialized medical providers.

One effective model is for an HIV medical provider to co-manage the patient with a primary care provider. In rural areas or other areas with low HIV prevalence rates, an HIV specialist may serve as a consultant to the primary care provider.

INFORMATION TECHNOLOGY FOR HIV MEDICINE

The American Academy of HIV Medicine (AAHIVM) and its members support the promotion of increased access to care and better care delivery through adoption of technological advances in medical records and information.

Medical information technology has the potential to improve comprehensive management of medical care and information for PLWHA.

Electronic medical records (EMR) are especially useful for the detailed and complex record keeping associated with managing HIV, provided that they contain the ability for providers to make extensive notes and record finely tuned medical treatments and regimens. However, access to electronic medical record systems can be unattainable for smaller provider offices not connected with a large medical network or hospital. The availability of health information technology (HIT) for these circumstances should be encouraged.

We also support the inter-connectivity of EMR systems so that there is efficient, accurate, safe, and cost-effective care of HIV patients across different health care organizations.

Portable personal electronic health records are another approach for HIV patients. The ability to transport the detailed record of medical history, drug regimens, and other treatments are invaluable for a patient with HIV facing relocation, travel, medical emergency, and incarceration. Likewise, electronic health information exchanges are especially helpful in these circumstances.

Another technological advancement which holds great promise for HIV care and treatment is telemedicine. We support efforts to promote tele-medicine technology which allow for the provision of HIV or other specialty care for populations who may otherwise not have access, such as those who reside in rural areas and correctional settings.

Although the Department of Health and Human Services has worked strenuously to encourage adoption of medical technology innovations, the HIV medical field has yet to benefit from some of the incentives to adopt these technologies.

The adoption of medical technologies in the HIV field should be incentivized with medical technologies and the exchange of medical information tailored to this mobile patient population. Specifically, there are three areas of medical technology which hold great promise for HIV care: electronic medical records, personal health records, and telemedicine.

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DRUG PRICING

The American Academy of HIV Medicine (AAHIVM) and its members support reasonable and affordable drug pricing that will ensure HIV patients have uninterrupted access to both the life-saving medications that are available today, and to those coming to market in the future.

As HIV care providers, we have significant concern over the ability of our patients to receive the medications they need. Promoting access to life-saving medications for PLWHA is one of our organizational principles. We hope to ensure all HIV-infected patients have access to all medications needed to optimize their health.

One of the chief barriers to this is the exceedingly high costs of many HIV drugs. The decrease in deaths brought about by Highly Active Anti-Retroviral Therapy (HAART) coupled with the steady number of new infections and the aggressive attempts to bring people into care have increased the number of Americans living with HIV/AIDS and requiring antiretroviral therapy.

The vision of a world without AIDS is tempered for too many HIV medical providers working on the frontlines of the HIV pandemic by the inability to offer the available advances in treating this diseases to their patients due to restrictions in accessibility. This situation is in part due to the exorbitant prices of some medications, which often render them unavailable to many patients.

The issue of accessibility of drugs as related to pricing also affects public and private payers and coverage programs. Among the HIV infected, there have historically been high rates of uninsured and under-insured individuals. Over half of the HIV population relies on Medicaid coverage. Ryan White Program-funded AIDS Drug Assistance Programs (ADAPs) have in some years had to resort to placing patients on waiting lists for treatments, even as their immune systems decline from HIV disease.

Even for those who have attained health coverage through the Affordable Care Act, treatment options are often mitigated by the financial calculations of the systems and payers of coverage, care and treatment. Although most insurers cover a majority of the antiretrovirals, some of the most commonly prescribed antiretrovirals are often placed on the highest cost sharing tiers, as insurers implement strategies to control the cost of managing a larger HIV patient population.

Effective HIV treatment depends upon making sure the most effective treatment options are available to prescribers in order to make the best treatment decisions for their patients.

We support research and development of new innovative drug therapies for HIV patients, and for their commonly co-occurring conditions with HIV.

Our organization appreciates the contributions of pharmaceutical companies to the remarkable scientific advancements in HIV medicine. Unprecedented scientific achievements have produced effective HIV treatment and prevention tools that allow leaders worldwide to envision an AIDS-free generation three decades into the HIV pandemic. For HIV researchers and clinicians, the overwhelming evidence that early and ongoing access to HIV treatment not only saves the lives of HIV-infected

individuals but dramatically reduces their risk of transmitting the virus to others heightens the urgency of dramatically improving access to HIV care and treatment.

There should be a balance between the needs of the HIV patient population and the business model of the pharmaceutical manufacturers who develop and market antiviral medications. The substantial costs to pharmaceutical companies of discovery, research and development processes of pharmaceutical drug innovation along with the costs of and clinical trials in the drug approval process are weighted against the potential for exponential profit if the drug successfully comes to market, secured by patent exclusivity agreements. Drug companies argue that if this incentive were removed (due to curtailing or capping of drug prices and therefore profits) the incentive for innovation would decrease as well.

We recognize that pharmaceutical companies have a business model to support, but believe a balance between profit, access and public health will produce the highest return on investment.

We urge pharmaceutical manufacturers to show restraint in the pricing of new drugs as they come to market.

In recent years, the price of HIV medications set a dangerous precedent for drug pricing. In 2012, a new ARV combination drug came to market with a price point nearly 40 percent higher than other previous combination medications, setting a new threshold for cost in HIV medications.

In 2014 and 2015, new curative HCV drugs came to market with price points that also represented staggering increases over the cost of previously available treatments. The high levels of HIV and HCV co-infection means that pricing for these medications also impacts a significant portion of the HIV-infected population.

With HIV disease still disproportionately affecting the poor in both the U.S. and worldwide, we see decisions like this as rendering the benefits of these drugs unavailable to many, and likely to contribute to further HIV-related disparities overall.

We urge pharmaceutical companies to set prices for new and existing agents at levels that support access for the populations most in need.

We urge pharmaceutical manufacturers to show restraint from price increases after a drug comes to market while still under patent exclusivity.

We recognize that holding prices constant or even reducing them is rare in industry practice and difficult to sustain in a competitive environment. However, it is common practice for drug companies to increase prices on drugs during the years they are under patent. Ultimately, this practice also impacts patients accessibility of these medical therapies.

We support efforts to ensure HIV antiretrovirals are available to low-income patients, and to those in resource-poor settings.

We urge pharmaceutical companies to participate in initiatives such as the HarborPath[5] program that streamlines access to antiretrovirals for people with HIV infection without insurance or with poor drug coverage. Participation by all pharmaceutical manufacturers in programs such as this is urgently needed to realize the potential of these important programs.

[5] https://www.harborpath.org/

We urge pharmaceutical companies to sustain and expand their co-pay assistance programs for insured patients who still struggle to afford their medications, as an effort to compensate for the disproportionate placement of HIV antiretrovirals on the highest cost sharing tiers.

We also urge industry, federal and state government entities, medical providers, philanthropists, and other stakeholders to work together to explore all options for lowering the costs of antiretroviral therapies and to identify solutions to ensuring access to HIV treatment for everyone who needs it.

We also support compromises between pharmaceutical companies and government and private payers that retain the incentive for development of new drugs, yet allow for HIV patients to access to needed medications.

We cautiously support innovative models of cooperation between pharmaceutical companies, insurers, and pharmacy benefit managers aimed at reducing cost to patients as long as such efforts do not limit patient access to necessary treatment options.

We support the efforts of those pharmaceutical companies that share patents and allow generic medication to be made available in resource poor countries.

AAHIVM encourages policies to adjust the cost of drugs to all insurers and care and treatment programs in order to ensure that HIV patients have access to the sustained and quality treatments that are necessary to improve health, prevent HIV disease progression, and reduce the number of new infections.

THE AGING HIV POPULATION

The American Academy of HIV Medicine (AAHIVM) and its members encourage development of resources to better treat and optimize health outcomes for older PLWHA.

More older Americans are now living with HIV/AIDS. In the early days of the HIV/AIDS epidemic, the disease was one of youth. Today, the demographics of HIV/AIDS are changing, as those who are infected with HIV/AIDS live for decades, and an increasing number of seniors become infected with HIV each year. Within the next few years, more than half of all people living with HIV will be over the age of 50[6].

The health and medical communities must begin to consider and account for this reality in such ways as to address the following: how the presence of both HIV and common diseases of older adults alter the optimal treatment of HIV and co-morbidities, and how to educate the HIV specialist and the generalist to best address (diagnose, treat, or refer) these multiple conditions. A new medical awareness should be cultivated of treating HIV "throughout the life span" as opposed to focusing on short term survival or urgent care, as persons living with HIV now have life spans measured in decades rather than years.

The coming influx of a generation of older HIV-infected patients also means that HIV care must adapt in terms of access to care, reimbursement and coordination of care models. As HIV/AIDS patients age (as with other individuals) the incidence of chronic and other diseases that disproportionally affect older adults also increase. It is not uncommon for individuals over the age of 50 who are living with HIV/AIDS to have two or more co-morbidities such as osteoarthritis, hypertension, diabetes and cardiovascular disease.

HIV medical care provision will need coordination with a variety of medical specialties geared toward the conditions of aging: geriatrics, cardiology, rheumatology, dental, pain management, orthopedics, and endocrinology specialties, among others. HIV/AIDS specialists and other specialists such as geriatricians should contribute to development of new guidelines for these complicating conditions.

Additionally, the federal government must prepare for the transition of thousands of HIV/AIDS patients into Medicare systems as the HIV-infected population ages. Reimbursement and provision of care in each system must be aligned to ensure smooth transition of patients between the programs.

Medicare providers must be prepared to assist with the care of patients from Ryan White clinics and other HIV care providers. Medicare providers may need further incentive to accept HIV patients. We must ensure that low/fixed income elderly don't lose access to care, medication, or case management services as they age and transition to Medicare programs.

We support policies to expand Medicare Part D coverage of all HIV medications and the medications for the most common co-infections of HIV on the Medicare formulary. We urge that coverage of these

[6] Abrass, Christine K., et al., 2011: "The HIV and Aging Consensus Project: Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV"

medications be included on coverage tiers that promote wide access by HIV-infected patients on the program.

We also applaud the “6 protected classes” model of coverage within the Medicare Part D program. We consider it an excellent model of access to treatment for HIV-infected patients

PRIORITIES FOR FUNDING FEDERAL HIV/AIDS PROGRAMS

The American Academy of HIV Medicine (AAHIVM) and its members support the adequate funding of federal programs for HIV/AIDS care and treatment.

Federal and state programs for HIV/AIDS have been chronically underfunded. This underfunding has real repercussions for the health and well-being of people infected with a potentially fatal virus.

Most HIV providers report that the Medicare, Medicaid, and Ryan White programs do not currently reimburse medical care at actual cost. This creates long-term sustainability issues for HIV clinics and practices.

The Centers for Disease Control and Prevention estimate that there are 50,000 new HIV infections per year in the United States. The need for care, treatment, and services for people living with HIV grows annually, but federal funding of HIV programs historically grows at a much slower rate.

One example of this is the Ryan White-funded AIDS Drug Assistance Programs (ADAPs). ADAPs are critical in providing medications to people living with HIV/AIDS who have no other access. Unfortunately, during various periods, state ADAPs have been forced to cut services by reducing eligibility criteria, changing formularies, and closing enrollment. In 2010, some states placed individuals on waiting lists to receive their life-saving and life-sustaining medications through this program. Though the 2010 waiting list crisis was ultimately resolved, this disturbing incident revealed how vulnerable these programs, and the services they provide, are to budgetary shortfalls.

Success at fighting HIV requires financial investment to help sustain a long-term effort against the disease. The federal government must ensure that people living with the disease have adequate access to care and treatment.

The American Academy of HIV Medicine (AAHIVM) and its members support the funding and provision of support services for PLWHA, provided that the funding of these programs does not come at the expense of provision of medical care.

People with HIV have many significant challenges. Many people living with HIV have other co-morbid conditions, such as mental health problems, or drug or alcohol addiction. In addition, poverty, unemployment, domestic violence, lack of access to food, housing, and transportation, and many other issues can prevent people from accessing health care. People with competing demands and challenges in meeting their basic needs for legal services, housing, food, and child care may also have problems staying in medical care.

Support services are important and valuable to many PLWHA, and we support funding of programs aimed at assisting with these patient challenges.

However, basic medical care and provision of core medical services for HIV disease is chronically underfunded by the US government. Many HIV programs are facing serious challenges covering the provision of core medical services, including critical components of the standard for HIV care, such as laboratory monitoring and provision of drug regimens for those who cannot afford it.

For example, within the context of the Ryan White program, core medical services are covered under funding from Part C of the program. Although services such as “medical nutrition therapy” and “medical transportation” are useful, most Part C clinics face serious challenges covering the current list of core medical services, including critical components of the standard for HIV care, such as laboratory monitoring.

We must support retention of funding intended for direct medical services, while also looking to provision of services like transportation and food services for people living with HIV in addition to their medical care and treatment.

CO-MORBIDIITES IN HIV MEDICINE

The American Academy of HIV Medicine (AAHIVM) and its members support medical and health policies that contribute to optimal health for patients with co-infections and co-occurring conditions common to HIV patients

As HIV medical providers we have a considerable concern about co-occurring conditions and diseases commonly found with HIV infection. With advances in patient treatment and care, co-morbidities for HIV can often become more threatening to individual health than HIV infection itself. Therefore, we have a great concern for care, treatment and outcomes of the most common co-morbidities of HIV, such as such as cardiovascular disease, tuberculosis, hepatitis, mental health conditions and substance abuse /addiction disorders.

We support policies which lead to better care and treatment for hepatitis infection, and increased attention on the commonality of HCV co-infection with HIV.

According to the Centers for Disease Control and Prevention, at least 25% of Americans with HIV/AIDS are co-infected with the hepatitis C virus (HCV) and up to 10% of people with HIV/AIDS are co- infected with chronic hepatitis B virus (HBV)

HCV is one of the main causes of chronic liver disease in the United States, and chronic hepatitis C infection is also the leading reason for liver transplantation. HCV and HBV damage the liver more rapidly in people with HIV/AIDS. For example, HIV/HCV co-infected persons have twice the risk of cirrhosis and a six-fold increased risk of liver failure compared to people with HCV alone. Further, the progression of HCV disease limits the liver's tolerance for HIV medications.

As antiretroviral therapy has allowed people with HIV/AIDS to live longer, end-stage liver disease secondary to HCV has become the leading cause of death among people with HIV/AIDS in multiple populations studied in the United States.

We support increased access to both rapid and regular forms of screening to identify HCV infection among patients as early as possible with subsequent access to staging tests such as Fibrosure, Fibroscan and liver biopsy to assess need for treatment. In addition to promoting patient health and well-being, there are potential cost-savings associated with screening HIV-positive individuals for HCV and treating their infections in a timely manner before cirrhosis and hepatocellular carcinoma (HCC) may occur.

In 2014, the approval of new HCV regimens comprised of all oral direct-acting antivirals (DAAs) has offered the possibility of a cure for HCV in most co-infected patients usually with a 12-24 week course of therapy. This represents a dramatic improvement over older treatment options in terms of duration of therapy, tolerability and likelihood of sustained virologic response (SVR) which equates with HCV cure which is now over 90 percent in the majority of co-infected individuals.

However, payers are restricting access to these curative measures to those at the most advanced levels of disease progression (those with Metavir F3 bridging fibrosis and F4 cirrhosis or advanced scarring of

the liver) for cost-containment reasons. We oppose policies limiting access to treatment based solely on budgetary restrictions instead of scientific and medical indications of treatment. We support initiation of HCV treatment for all "except those with a limited life expectancy (less than 12 months) due to non-liver-related co-morbid conditions" as indicated by current medical treatment guidelines.[7]

We support policies which lead to better care and treatment for mental health and substance abuse conditions, and increased attention on the commonality of co-occurrence with HIV.

Because of the complex nature of HIV disease and the populations most vulnerable to it, there is an increased occurrence of mental health, substance abuse, and other conditions among HIV patients. We support policies and programs that address this. Identifying and treating co-occurring conditions requires that all medical and social service providers recognize the impact of these conditions on persons living with HIV/AIDS. Proper training, support, and integration of appropriate services by mental health professionals (screening, prevention, surveillance, referral, treatment, and case management) into their existing HIV programs is needed.

We support policies which lead to better care and treatment for cardiovascular disease among HIV-infected patients.

Increasingly, studies reveal that persons living with long-term HIV infection are at increased risk for the development of cardiovascular disease including myocardial infarction and stroke. Additionally, long-term exposure to antiretroviral medications may increase the risk for CVD and associated complications.

There is a growing need for increased cardiovascular risk factor screening and appropriate risk reduction strategies among HIV-infected patients. We support policies to increase and prioritize access to diagnosis and treatment of co-occurring cardio vascular conditions among HIV-infected patients

[7] AASLD/IDSA guidelines at HCVguidelines.org

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HIV TESTING

The American Academy of HIV Medicine (AAHIVM) and its members support the implementation of routine HIV testing for all patients in medical settings, as recommended by the Centers for Disease Control and Prevention (CDC).

AAHIVM supports continued efforts to promote the 2006 Centers for Disease Control and Prevention (CDC) Revised Recommendations on HIV Testing. In 2012, the U.S. Preventative Task force also released a statement recommending routine HIV screening in all Americans aged 15 to 65. We fully support the goal of routine HIV screening in the U.S. and urge all Americans to learn their HIV status.

HIV testing has enabled individuals with HIV to become aware of their health status and to take appropriate precautions to preserve their health. Screening and treating expectant mothers during pregnancy is now one of the major successes of the HIV world. The strategic use of medications and biomedical interventions has allowed us to nearly eliminate HIV transmission to newborns in the US to less than 2% of births annually. Despite advancements in the area of prenatal screenings, adolescents and many other patient groups are still not being tested. When individuals learn their HIV status, they change their behavior to protect their partners and to help themselves. Moreover, studies show that individuals diagnosed with HIV take steps to reduce the likelihood of transmitting HIV to others.

Too many people living with HIV are unaware of their status: An estimated 15 percent of people with HIV in the United States do not know their status. Studies show that people who do not know that they are HIV-positive are more likely to engage in risk behaviors associated with HIV transmission. Many of these individuals are already accessing health care services, but opportunities to diagnose them are being missed.

Continued evidence from many HIV providers indicates that the CDC message of universal testing for all adults ages 13-64 is not getting through to medical providers outside the HIV community. Continued education on universal HIV testing guidelines for providers in non-HIV specialties is desperately needed.

AAHIVM support policies that promote reimbursement for HIV testing by all payers.

AAHIVM believes that confidence in reimbursement can help ally provider concerns about the cost of routine testing.

We strongly urge all federal departments to recognize the importance of implementing routine HIV testing in health care settings through coverage and reimbursement policies under federal programs. Many private insurance companies base their reimbursement schedule on CMS reimbursements.

Medicaid is the primary health coverage for the majority of persons living with HIV/AIDS in the U.S. National coverage by Medicaid for HIV infection screening would likely serve to encourage other insurers to cover routine HIV testing as well. Providers that treat Medicaid patients need to feel confident that they will be reimbursed when testing is performed.

AAHIVM supports policy and legislative changes in accordance with CDC recommendations on HIV test counseling, and consent procedures.

Some states still have laws that are not fully compatible with CDC recommendations in the areas of counseling and consent related to HIV testing. This may impede broad HIV testing efforts. We encourage lawmakers to work with state AIDS officials to update state laws in this area to further promote adoption of CDC recommendations on routine HIV testing.

As such, we support efforts to eliminate required separate written consent requirements for HIV testing in the states that still require this. At all times, we also support informed consent testing practices. However, separate written consent requirements have been shown to be a barrier to routine testing efforts.

We do not support policies mandating pre- or post-test counseling for HIV testing. Instead, we encourage providers to follow medical best practices, and to use their professional discretion in offering supportive counseling to patients who desire it.

AAHIVM supports protection of patient privacy, and protections against the disclosure of individual private medical information.

We encourage maintenance of HIPAA standards of protection over disclosure of individual health information. Especially in the area of HIV testing, disclosure of individual test results must be protected vigilantly by test administrators.

AAHIVM supports initiatives the promote linkage to care following HIV testing.

A major downfall of testing efforts across the nation is the failure to reliably link individuals diagnosed with HIV to experienced HIV care providers and other critical HIV-related services following testing, and to retain them in care. Prevention efforts should include a focus on the necessary infrastructure to link individuals who undergo HIV testing to both medical and behavioral health care following a diagnosis. Those who are receive a negative outcome to HIV testing should also be linked to care for further medical guidance on how to avoid transmission, and to promote appropriate testing in the future.

We support policies that encourage referral to an HIV Specialist following HIV testing for those determined to be HIV positive.

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OVER-THE-COUNTER AND HOME HIV TESTING

The American Academy of HIV Medicine (AAHIVM) and its members support advances in HIV testing technologies and policies that promote the ability of patients to voluntarily and confidentially learn their HIV status through regular and accessible testing. We also support, to the greatest extent, the linkage of these innovations to medical care as well as unburdened access to counseling and prevention/risk-reduction information.

AAHIVM supports the 2006 Centers for Disease Control and Prevention (CDC) Revised Recommendations on HIV Testing. We fully support the goal of routine HIV screening in the U.S. and urge all Americans to learn their HIV status.

HIV testing has enabled individuals with HIV to become aware of their health status and to take appropriate precautions to preserve their health as well as the health of others.

However, despite advancements in the area of testing and screenings, many at-risk groups are still not being tested. An estimated 15 percent of people with HIV in the United States do not know their status, and many of these individuals are already accessing health care services. Opportunities to diagnose many HIV-positive individuals are still being missed.

Testing is an important principle of HIV prevention; according to research, when individuals learn their HIV status, they change their behavior to protect their partners and reduce transmissions. Studies also show that people who do not know that they are HIV-positive are more likely to engage in high-risk behaviors associated with HIV transmission.

Providing infected individuals with regular medical care and treatment involves reliably linking individuals diagnosed with HIV to experienced HIV care providers and other critical HIV-related services. Prevention efforts have focused in recent years on the importance of linking HIV testing to both medical and behavioral health care following a diagnosis.

“At-home” or “over-the-counter” (OTC) HIV testing has been a subject of discussion and debate for many years among HIV advocates, providers and the larger public. The first OTC HIV test designed for wide-spread use was approved by the FDA in 2012[8] and is widely available in pharmacies.

AAHIVM generally supports innovations (and has been involved in efforts) that promote widespread, confidential and voluntary HIV testing and individual knowledge of HIV status.

However, we recognize that there may be risks associated with testing at home that in some cases would be mitigated in the medical setting. Still, we do not believe these concerns necessarily outweigh

[8] Ora-Quick TM

the impact of making confidential, voluntary HIV testing more available to individuals and we encourage manufacturers of the tests to account for these concerns whenever possible:

We encourage efforts to link individuals using OTC tests to well-trained counselors who are available via phone and internet around the clock and also to link patients to local medical care for confirmation of their diagnosis and treatment. This can be done through the use of a toll free number or a link to a website such as aahivm.org. General information regarding HIV, treatment, and resources can be made available with the kit in multiple languages.

The first company to market such a test provides 24/7 bilingual counseling and referrals to local HIV providers.[9] We support this model.

Even when over the counter HIV tests have a high sensitivity and a high specificity, when a large population is tested when there is a low incidence of disease, there is potential for false positive and false negative results. Manufacturers are encouraged to explain what this means and that the test result is only preliminary. Confirmation of a positive test should be done by a medical professional as soon as possible. Links to medical settings that offer confirmatory testing services should be made available through website or toll-free numbers provided with the test kits.

We also have some concern about the potential for coercion or domestic violence occurring in unregulated testing settings. For example sex workers could be forced to test and may be harmed if a test is positive. The same is true of domestic partners. The potential for disclosure to individuals other than the individual tested is also a concern. We encourage that producers of at-home tests to consider and minimize possible social harm scenarios by conducting post marketing research in different populations and responding to the results accordingly.

Finally, some researchers have expressed concern about study participants testing themselves outside of the study visits. This could impact blinding in vaccine trials and endpoints and follow up in other prevention trials. Designers of study protocols should take into account this possibility in the design of studies and counseling of participants. We also encourage makers of OTC testing products to coordinate with researchers and study sponsors to measure the effects of such events where possible

[9] Ora-Quick TM

HIV RESEARCH

The American Academy of HIV Medicine (AAHIVM) and its members support research efforts that lead to the better care, treatment of patients, and prevention of the disease. As such, we support abundant funding of a robust research agenda by the federal government and also the funding of research by private organizations and individuals.

Research remains essential to finding a cure for HIV and to developing safer, more effective therapies and regimens to treat HIV and its associated complications.

A strong research agenda is the final step in all efforts to curb the disease. We urge the Administration to encourage and support innovative research not only into diagnosis, treatment and prevention, but also into the social and epidemiological factors of the disease that weave the complex tapestry that is HIV/AIDS in the U.S. in the twenty-first century.

Research in Medicine: Research into the co-morbid conditions associated with living long-term with HIV is a topic of great interest to HIV providers. A few specific subjects of medical research that would benefit from increased understanding are: co-morbidities associated with aging with for HIV, malignancy, cardiovascular disease, renal disease, hyperlipidemia, diabetes, osteoporosis, and hepatitis B and C co-infection, among others. We also have a desire to see research into drug interactions antiretrovirals and other medications commonly used to treat heart disease, lipid disorders, dementia, and psychiatric conditions. However, in all research forums, we see a need for stronger representation by non-white, non-male participants to accurately reflect the changing face of HIV in the U.S.

Research in Demographics and Human Behavior: We would like to see new studies based on emerging locations and populations affected by HIV. The disease has migrated into new populations and locations over the past decade though studies have not kept pace with this changing epidemiology. While studies are abundant on urban Caucasian gay men, research is sparse on other HIV-infected populations such as black men who have sex with men (MSM), women, indigent and migrant populations, transgender populations, and also on HIV in the rural South and central portions of United States. We encourage researchers to further examine the disease in these populations and locations and to support a research platform that more fully reflects the changing identity of the epidemic. We support both quantitative and qualitative research in HIV. We especially support probability sampling techniques that are used in RCTs (randomized controlled trials) when studying hard-to-reach populations

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HIV EDUCATION AND PREVENTION

The American Academy of HIV Medicine (AAHIVM) and its members support policies that increase HIV awareness and education among the general public, our patients, and all care providers. We also support polices that lead to prevention of the spread of the disease through education and other efforts.

Great strides have been made in treating HIV over the past 18 years, yet this very success can become grounds for complacency. We are seeing the proliferation of drug-resistant strains of HIV and a steady increase in HIV transmission (often by people who do not know that they are infected).

Too many Americans do not have the basic facts about HIV and other sexually transmitted infections. It is essential that all Americans have access to shared factual information about HIV and the current HIV epidemic. This includes knowing how HIV is transmitted and prevented and also knowing which behaviors place individuals at greatest risk for infection. While we recognize that HIV is concentrated in certain communities, we support providing all Americans with clear information about how to avoid HIV infection.

Our first duty as HIV health care providers is to maintain vigilance against complacency about this life-threatening contagious illness. We must educate policy makers that testing and prompt treatment is vital to reducing the spread of HIV. The best strategy for HIV is prevention, and the best prevention is early detection and appropriate treatment of all people infected with this often-fatal disease.

Broader HIV education is needed across the age span. Currently, half of all Americans living with are nearing age 50, and 15 percent of new HIV cases occur in this age group. Education is needed to effectively encourage people across the age span to take steps to reduce their risk for infection.

HIV awareness and education should be universally integrated into all medical environments and health and wellness initiatives. Information about HIV is important to include in any wellness context promoting healthy behaviors, including sexual health. We must also ensure that all health and wellness practitioners (peer counselors, intake specialists, doctors, physician assistants, nurse practitioners, nurses, and other health professionals) are also educated about HIV, especially in programs for underserved communities.

Since HIV treatment of HIV prevents new infections, we support education of primary care providers on adopting the CDC recommendations for opt out testing of all of their patients for HIV. In addition, we support the education of primary care providers and others to become knowledgeable about pre-exposure prophylaxis of HIV (PrEP) and post-exposure prophylaxis (PEP) two proven strategies that can help reduce the transmission of HIV.

We should ensure that this education reaches populations that may be overlooked. The focus of the education and awareness effort is to improve individual understanding of HIV infection, HIV-related risk factors and risk reduction, and HIV-related stigma and discrimination.

We must also move away from thinking that one approach to HIV prevention will work, whether it is condoms, education, or pre and post-exposure prophylaxis. Instead, we need to develop, evaluate, and implement effective prevention strategies and combinations of approaches including expanded HIV testing, education and support to encourage people to reduce risky behaviors, the strategic use of medications and biomedical interventions, the development of vaccines and microbicides, and the expansion of evidence-based mental health and substance abuse prevention and treatment program

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HARM REDUCTION

The American Academy of HIV Medicine (AAHIVM) and its members support policies that promote harm reduction strategies for people who engage in high-risk behaviors involving injection drug use.

Harm reduction (or harm minimization) refers to a range of public health policies designed to reduce the harmful consequences associated with recreational drug use and other high risk activities. Harm reduction is a set of practical strategies that reduce negative consequences of drug use, by utilizing a spectrum of strategies that range from safer use, to managed use, to abstinence.

The use of certain illicit drugs often involves self-injection using hypodermic syringes. In some areas, these syringes are available solely by prescription. When availability is limited, users of heroin and other drugs frequently share their syringes and use them more than once. As a result, one user's infection (such as HIV or Hepatitis C) can spread to other users through the reuse of syringes contaminated with infected blood. The principles of harm reduction propose that clean syringes should be available without a prescription or at least available through a Needle and Syringe Exchange (NSE) program.

AAHIVM supports access to sterile needles and syringes as one method of preventing HIV transmission.

Injection drug use remains a substantial driver of the HIV/AIDS epidemic in the United States, and the leading cause of new hepatitis C infections. Among injection drug users, sharing needles and other drug paraphernalia increases the risk of HIV infection. Abundant research, endorsed by the findings of eight federally commissioned reviews, has conclusively demonstrated that syringe exchange is effective in reducing the transmission of HIV without increasing drug use. Studies have also found that providing sterile equipment to injection drug users increases the probability that they will initiate drug treatment, and does not increase drug use.

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MEDICAL MARIJUANA

The American Academy of HIV Medicine (AAHIVM) and its members support the ability of medical providers to determine the best course of treatment for their patients on an individualized basis, within the context of the law.

Medical marijuana is a highly charged policy topic on both state and federal levels. Marijuana was used medically in the U.S. until the late 1930s. In 1970, U.S. drug law classified marijuana as having a high potential for abuse and having no valid medical use. Today, with some exceptions, Federal and State laws generally forbid the sale or possession of marijuana. Twenty three states and the District of Columbia have passed medical marijuana laws that permit limited use for health reasons. In 2009, the US government announced that federal agents will not arrest medical marijuana patients or providers who comply with state laws.

Marijuana has been found to have various health benefits. It reduces muscle spasms in people with neurologic disorders and can help treat some types of pain including that from peripheral neuropathy. Many scientific studies document marijuana's ability to reduce nausea and increase appetite. Some HIV patients also report experiencing a poor appetite due to fatigue or drug side effects. Poor appetite can contribute to a condition known as “AIDS wasting.” Some people with HIV experience nausea when taking antiretroviral medications (ARVs), which can make it difficult to consistently take all scheduled doses of life-sustaining medications. Missing medication doses decreases the effectiveness of treatment regimens and raises the possibility of medication resistance.

There is a need for further research into uses and health benefits of marijuana for HIV patients. Very few formal studies have been done on the utility of most herbs and herbal supplements. Additionally, few studies are available on the interactions between the use of herbs and common medications. One research study found that smoking marijuana does not increase HIV viral load or reduce CD4 cell counts. However, smoking any substance presents some health concerns for people living with HIV, including respiratory infections and emphysema. More studies are absolutely needed to determine the risk versus benefit as a treatment alternative for people living with HIV.[10]Further research that examines the biochemical properties of marijuana and their interaction with the endocannabinoid system are necessary to determine if safer delivery methods can be discovered.

Ultimately, we support the ability of medical providers to determine the best course of treatment for their patients on an individualized basis, within the context of the law. And we support research into the risks and benefits of marijuana as a treatment option for people living with HIV.

We support the ability of state and federal lawmakers to determine the legality of use and possession of marijuana for medical purposes.

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[10] “Association Between Marijuana Exposure and Pulmonary Function Over 20 Years” Mark J. Pletcher, MD, MPH; Eric Vittinghoff, PhD; Ravi Kalhan, MD, MS; Joshua Richman, MD, PhD; Monika Safford, MD; Stephen Sidney, MD, MPH; Feng Lin, MS; Stefan Kertesz, MD

We also support policies that increase the ability of providers to prescribe optimal treatments for the medical well-being of HIV and AIDS patients

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HIV CRIMINALIZATION

The American Academy of HIV Medicine (AAHIVM) and its members are opposed to laws that distinguish HIV disease from other comparable diseases or that create disproportionate penalties for disclosure, exposure or transmission of HIV disease beyond normal public health ordinances. We support non-punitive prevention approaches to HIV centered on current scientific understanding and evidence based research.

The criminalization of HIV transmission and exposure is a complex issue. Early in the history of the HIV epidemic, public fear of the disease led many states to pass laws that established criminal penalties for failing to disclose infection, for exposing others to the disease, and for transmitting the disease intentionally or unintentionally. In many cases, these laws apply regardless of protective measures the HIV-positive person may take.

At the time when many of these laws were passed the routes of HIV transmission, and methods of preventing the disease were not as well understood scientifically as they are today. In some cases, these laws reflect assumptions about the disease that are now known to be scientifically invalid. For example, some state laws criminalize biting or spitting by HIV-positive persons, even though saliva is not considered a probable transmission risk.

These laws are specific to HIV and the same standard is not applied to other diseases such as hepatitis C and hepatitis B which can also be transmitted via sexual activity.

Currently, 34 states and two U.S. territories have laws which criminalize behavior of HIV positive people. The laws are varied in detail, but many are harsh in nature with some having penalties, including incarceration, that are usually reserved for the most serious of crimes. Many of these laws are applicable whether or not actual harm has been demonstrated or caused. This seems to be disproportionate punishment that arises from hysteria and/or homophobia.

The subsequent prosecutions that have resulted from these laws, and the juridical policy that has been built upon on these laws are similarly flawed in their presuppositions, motives, and utility.

They also fail to take into account the major advances in HIV care and treatment that are now available to those who do become infected. HIV disease is in most cases today a manageable long-term condition. However, prosecutorial precedent still treats transmission of the disease as the equivalent of a death sentence, which represents a significant exaggeration in the current medical environment.

As medical professionals, our members support policies that encourage individuals to learn their HIV status, participate in regular medical care, and take measures to protect others against the spread of the disease without punitive sanctions.

Our members oppose public policies and laws that distinguish HIV disease from other comparable diseases, and believe public health and juridical policy on HIV should be no different to that of other sexually transmitted or communicable diseases, such as tuberculosis, hepatitis, herpes or syphilis.

Public health policies, and laws (as well as possible prosecutions that might result from those laws) should take into account the most up-to-date scientific information about methods of transmission and prevention, as well as the great advances in care and treatment that are now available to those who do become infected with HIV, which in today's world is usually a treatable long term condition.

In some rare cases, there may be a role for legal redress against individuals who transmit the disease or expose others to the disease with malicious intent. There may also be a role for legal redress when an individual seeks to defraud another individual concerning their health status. However, pathways for such legal redress already exist in most states. Redundant laws focused on one disease are unnecessary, stigmatizing, harmful and unjust.

Policies on HIV should also take into account the high levels of stigma and prejudice still associated with the disease, and seek to protect individual privacy, rights, and freedom.

Public policies, and laws around disease transmission should be evidence-based and non-discriminatory in nature. They should serve public health goals and promote public awareness.

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HIV-INFECTED HEALTH CARE WORKERS

The American Academy of HIV Medicine (AAHIVM) and its members are opposed to workplace policies that distinguish HIV disease from other comparable diseases as it relates to employment.

The American Academy of HIV Medicine believes that HIV should be treated no differently than any other illness as relates to employment.

We fully embrace the protections accorded by the Americans with Disability Act and support all protections of privacy from disclosure about one's HIV status to an employer.

As in the case of any illness, we support the concept as required by the Joint Commission on Accreditation of Health Care Organizations, most hospitals and other health care organizations to ask only that a health care worker is physically and mentally capable of performing the duties of their job, and see no justifiable reason for a health care worker, or any other worker to be asked to disclose their status of HIV infection to their employer

GENERIC HIV DRUGS

The American Academy of HIV Medicine (AAHIVM) and its members support the optimal individualized use of an ART regimen for each patient. This may include use of generics but only after full examination of the true cost of a regimen taking into account adherence, toxicity, cost, efficacy, and test monitoring along with the risks of treatment failure, resistance, and viral transmission.

The tremendous advances we have made in health outcomes and decreases in mortality from HIV have been largely related to innovations in ART.

Adherence is strongly associated with likelihood and durability of viral suppression as well as clinical outcomes, including development of treatment resistance, morbidity and hospitalization rate. Current HIV treatment guidelines support combination tablets, daily dosing and Single Tablet Regimens (STRs) based on evidence supporting their improved tolerability and demonstrated superior adherence by patients. Data demonstrate that interruptions in adherence or only partial adherence is associated with increased hospitalization.[11]

In recent years, some HIV medications have moved off patented status, allowing for the very first generic HIV medications to be developed in the 30 year history of this disease. This represents the start of a fundamental shift in available treatment options for HIV patients.

AAHIVM supports the use of DHHS Treatment Guidelines in determining patient care.

However, none of those newly generic medications are currently included as preferred treatment options in the 2017 DHHS Guidelines for HIV Treatment. At most, some of the newly generic medication represent one component of a combination ARV treatment that is normally prescribed as a single-table regimen (STR). Currently and for the foreseeable future, there is no prospect for a “preferred” STR generic regimen.

ARVs that have recently or will soon become generic such as efavirenz and lopinavir/ritonavir have moved off the “preferred” list of ARVs. Likewise, with the development of tenofovir alafenamide, the use of tenofovir disoproxil fumerate is also in sharp decline.

In order to utilize prescription of the generic medication, in accordance with current HIV treatment guidelines, a patient would have to be prescribed a multi-tablet regimen including all of the component medications. This raises two important questions for consideration. It is questionable whether the overall cost of the regimen when broken into components, only one

[11] Cohen, BMJ Open. 2013; 3(8)

of which is generic, will be substantially lower and therefore offer a true cost-savings to the payer.

Far more important is the question of the impact of the multi-component regimen on patient utilization and adherence. Current DHHS Guidelines on HIV Treatment make specific reference to the importance of adherence and tolerability in HIV treatment decisions.

A meta-analysis has shown that use of preferred antiretroviral combinations leads to improved efficacy compared with alternative regimens.[12] HIV medical care providers must be allowed access to preferred regimens for this reason, regardless of cost consideration

In general AAHIVM supports initiatives that improve value and cost-reduction within a health care system. However, as medical providers, our primary concern is always patient health and well-being.

Generic medications can in some cases represent cost-savings to health insurance coverage providers and others payers of patient health care. In general, AAHIVM recognizes the interests and needs of programs and payers to keep costs for treatment low and to maximize resources. This interest take a very real form in the case of programs such as the Ryan White AIDS Drug Assistance Programs (ADAP).

While cost savings are the major driver behind adoption of generic antiretroviral drugs, the magnitude of the actual benefit is uncertain. Cost analysis must not be limited to the cost of ARVs alone, but must also account for all associated costs:

- The costs associated with treatment failure (disease progression, medication to treat opportunistic infections and diseases, hospitalizations and increased outpatient treatment costs, increased cost associated with second and later courses of therapy, especially if drug resistant virus emerges)
- The public health and societal costs (cost of treatment of HIV lifelong for any partners who may become infected, possible transmission of drug resistant virus, time lost from work/productivity due to illness, reversal of trends in declining HIV incidence)
- The increased cost of enhanced monitoring and management of side effects of potentially more toxic older treatments (laboratory screening, more frequent outpatient visits, DEXA scans, medications to treat toxic effects such as proteinuria, depression, neuropathy, lipodystrophy, dyslipidemia, osteoporosis, renal failure, etc.)[13]

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[12] Lee et al, PLoS ONE 9(5): e97482. doi:10.1371/journal.pone.0097482

[13] Citation: E. Sweet D, L. Altice F, J. Cohen C,
Vandewalle B (2016) Cost-Effectiveness of Single- Versus Generic Multiple-Tablet Regimens for Treatment of HIV-1 Infection in the United States. PLoS ONE 11(1): e0147821. doi:10.1371/journal.
pone.0147821

Estimate of actual medication cost savings with switch to generic ARVs may be overstated. Many people living with HIV receive medication through programs that already sharply discount the cost of medications through negotiated rates or other discounts. Some pharmaceutical companies offer co-pay assistance cards to cover all or most of these co-pays. Manufacturers of generic drugs do not offer such co-pay assistance cards, so the patient will now have to assume that cost completely. Paradoxically, out of pocket costs to patients may actually increase with the introduction of generics into widespread prescription.

Furthermore, according to FDA analysis, the price of generic drugs is often minimally reduced compared to the brand product if only a single generic manufacturer is in the market. It is only after a second or third manufacturer enters production that the level of competition becomes strong enough to realize significant cost reductions and savings from generics.[14]

[14] https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm

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UNTRANSMISSABLE STATUS

The American Academy of HIV Medicine (AAHIVM) and its members support scientific data that indicate a greatly diminished risk of HIV transmission for those persons who maintain long term HIV viral suppression.

Leading public health experts affirm that there is sufficient scientific evidence supporting the medical position that a person living with HIV who is on antiretroviral therapy (ART) and is durably virally suppressed (defined as having a consistent viral load of less than <200 copies/ml) has a profoundly minimized risk of sexually transmitting the HIV virus, designated herein as "**untransmissable**."

The American Academy of HIV Medicine (AAHIVM) and its members emphasize the conditionality of the "untransmissable" status, and the need for ongoing medical monitoring for all patients living with HIV.

This designation is subject to a number of specific patient indicators, such as adherence, uptake, response to medication, development of resistance to treatment, as well as, other patient co-morbidities.
The importance of consistent adherence to a successful ART regimen, and close regular medical monitoring for changes in HIV viral load and medical status cannot be over-emphasized. A designation of "untransmissable," once designated, can also be lost in some cases.

The American Academy of HIV Medicine (AAHIVM) and its members support the advancement of information to HIV patients regarding the reduced likelihood of HIV transmission once a person reaches "undetectable" status.

The preventative benefits of highly effective ART provides an unprecedented opportunity to improve the lives of people living with HIV. An increased public awareness through dissemination of information to patients regarding these benefits may offer public health opportunities. These opportunities include the potential for increased HIV diagnosis and screening, improved treatment adherence, and support for expanded access to treatment and care.
A broadened awareness of this information also offers opportunities to reduce stigma of the disease both in the public perception, and for individual patients and their partners. The message of "untransmissable" status may serve to promote encouragement for some patient to initiate and adhere to an ART regimen. This includes closely monitoring their viral load, and engagement in regular medical care.

Partners of patients with "untransmissable" status may additionally benefit from the "untransmissable" status. They may consider discontinuing their PrEP usage following achievement of untransmissability, absent of other risk factors.
The American Academy of HIV Medicine (AAHIVM) and its members support the continued need for individual consultation with patients that addresses the specific probability of "untransmissable" status. The AAHIVM also generally supports carefully crafted public health messages related to this subject.

While "untransmissable" public health messaging and campaigns may offer substantial promise for education and awareness of this subject, AAHIVM maintains concern for emphasizing the specific individuality of each patient.

HIV is not a one-size fits all disease. Communicating the need for ongoing medical management and monitoring to each patient is of paramount importance. It is the role of HIV medical care providers to educate their patients concerning their specific health status, as well as, progress in treating and suppressing their virus.

The American Academy of HIV Medicine (AAHIVM) and its members support continued need for concurrent messaging concerning other HIV prevention methods such as condom usage and PrEP, in tandem with "untransmissable" status messaging.

Although the "untransmissable" message holds great promise, that message must be relayed in context with other risk factors and HIV prevention methods, such as PrEP and condom usage.

The American Academy of HIV Medicine (AAHIVM) and its members support continued need for concurrent messaging concerning other risk factors for HIV transmission. This includes other sexually transmitted infections (STIs) and HIV related diseases.

The "untransmissable" message must be placed in context as it applies only to HIV transmission, and not to other STIs.

It must also be presented within the context of applicability to sexual transmission of HIV, and not imply invulnerability to risk of infection through other risk factors such as needle sharing.

It is important to note that while viral suppression prevents the transmission of HIV, consistent and correct condom use and pre-exposure prophylaxis (PrEP) also prevent the transmission of HIV. Condoms provide additional protection for other STIs and pregnancy.

The AAHIVM supports promotion of public education that increases proper medical, scientific, and evidence-based understanding of HIV disease. It also supports decreasing the stigma associated with living with HIV, as well as, opportunities for HIV patients to live full and happy lives.