

# **Presidential Advisory Council on HIV/AIDS (PACHA)**

## **76<sup>th</sup> Meeting**

**U.S. Department of Health and Human Services**

**200 Independence Avenue, SW**

**Washington, DC**

**March 29–30, 2023**

### **Council Members—Present**

Marlene McNeese, PACHA Co-Chair, Assistant Director, Houston Health Department, Houston, TX

John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chair, Professor, Gillings School of Global Public Health, Health Policy and Management, The University of North Carolina at Chapel Hill, Chapel Hill, NC

Tori Cooper, M.P.H., Director of Community Engagement for the Transgender Justice Initiative, Human Rights Campaign, College Park, GA (*day 1 only*)

Alicia Diggs, M.P.H., Manager, Office of Community Engagement, Center for AIDS Research, The University of North Carolina at Chapel Hill, Greensboro, NC

Vincent Guillamo-Ramos, Ph.D., M.P.H., LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN, Dean and Professor, Duke University School of Nursing, Vice Chancellor, Nursing Affairs, Duke University, Durham, NC

Jennifer Kates, Ph.D., Senior Vice President and Director of Global Health & HIV Policy, Kaiser Family Foundation, Washington, DC

Marc Meachem, M.B.A., Head, External Affairs, ViiV Healthcare North America, Washington, DC

Leo Moore, M.D., M.S.H.P.M., Medical Director for Clinic Services, Los Angeles County Department of Public Health, Los Angeles, CA

Rafaelé Narváez, Co-Founder and Director of Health Programs, Latinos Salud, Wilton Manors, FL

Laura Platero, J.D., Executive Director, Northwest Portland Area Indian Health Board, Portland, OR

Michael Saag, M.D., Associate Dean, Global Health, School of Medicine, and Professor of Medicine, Division of Infectious Disease, The University of Alabama at Birmingham (UAB); Director, UAB Center for AIDS Research, Birmingham, AL

Carl Schmid, M.B.A., Executive Director, HIV+Hepatitis Policy Institute, Washington, DC

Justin C. Smith, M.S., M.P.H., Director, Campaign to End AIDS, Positive Impact Health Centers, Atlanta, GA

Ada Stewart, M.D., RPh, FAAFP, AAHIVS, HMDC, Lead Provider and HIV Specialist, Eau Claire Cooperative Health Centers (Now Cooperative Health), Columbia, SC

Darrell P. Wheeler, Ph.D., M.P.H., M.S.W., Provost and Senior Vice President for Academic Affairs, Iona College, New Rochelle, NY

### **Council Members—Absent**

Gregg H. Alton, J.D., San Francisco, CA

Guillermo Chacón, President, Latino Commission on AIDS; Founder, Hispanic Health Network, New York City, NY

Raniyah Copeland, M.P.H., Principal, Equity & Impact Solutions, Los Angeles, CA  
Kayla Quimbley, National Youth HIV and AIDS Awareness Day Ambassador, Advocates for Youth, Columbus, GA  
John Saperro, Director, Ending the HIV Epidemic, Collaborative Research LLC, Phoenix, AZ

**Liaison: Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and Sexually Transmitted Disease (STD) Prevention and Treatment**

Wendy Armstrong, M.D., FIDSA, Professor of Medicine, Emory University; Executive Medical Director, Ponce de Leon Center, Grady Health System, Atlanta, GA

**Staff**

B. Kaye Hayes, M.P.A., PACHA Executive Director, Designated Federal Officer; Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP); Deputy Assistant Secretary for Infectious Disease - Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS)  
Caroline Talev, M.P.A., PACHA Committee Manager, Senior Management Analyst, OIDP, OASH, HHS

**Federal Partners**

Demetre Daskalakis, M.D., M.P.H., White House National Monkeypox Response Deputy Coordinator, Director, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB [Tuberculosis] Prevention (NCHHSTP), CDC  
Lee A. Fleisher, M.D., Chief Medical Officer and Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services (CMS) (*day 1 only*)  
Rita Harcrow, Director, Office of HIV/AIDS and Housing, U.S. Department of Urban Development (HUD) (*day 1 only*)  
Timothy Harrison, Ph.D., Principal Deputy Director, OIDP, HHS  
Heather Hauck, M.S.W., LICSW, Deputy Associate Administrator, HIV/AIDS Bureau, HRSA  
Rick Haverkate, M.P.H., National HIV/AIDS & Hepatitis C Program Coordinator, Indian Health Service (IHS)  
RDML Timothy H. Holtz, M.D., M.P.H., FACP, FACPM, U.S. Public Health Service (USPHS), Deputy Director, Office of AIDS Research (OAR), National Institutes of Health (NIH)  
Ernia P. Hughes, M.B.A., Director, Office of Health Center Investment Oversight, Bureau of Primary Health Care (BPHC), HRSA (*day 1 only*)  
Jessica Lee, Medical Officer, Center for Medicaid and Children's Health Insurance Program Services, CMS (*day 1 only*)  
Peter Marks, Director, Center for Biologics, U.S. Food and Drug Administration (FDA) (*day 2 only*)  
RADM Jonathan Mermin, M.D., M.P.H., USPHS, Director, NCHHSTP, CDC (*day 2 only*)  
Robyn Neblett-Fanfair, M.D., M.P.H., Principal Deputy Director, NCHHSTP, CDC  
Harold J. Phillips, M.R.P., Director, White House Office of National AIDS Policy (ONAP)  
Jirair Ratevosian, Senior Advisor, Office of the Global AIDS Coordinator, U.S. Department of State (*day 2 only*)

Kristin Roha, M.S., M.P.H., Public Health Advisor for HIV, Substance Abuse and Mental Health Services Administration (SAMHSA)  
Adrian Shanker, Senior Advisor, LGBTQI+ (lesbian, gay, bisexual, transgender, queer, and intersex) Health Equity, OASH, HHS (*day 2 only*)  
Edwin Walker, J.D., Deputy Assistant Secretary for Aging, Administration for Community Living (ACL), HHS (*day 1 only*)  
CAPT Samuel Wu, Pharm.D., USPHS, Public Health Advisor, Office of Minority Health, HHS

## Day 1

### Opening Remarks from the PACHA Co-Chairs

*Marlene McNeese and John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chairs*

Ms. McNeese called the meeting to order at 9:01 a.m. ET. She explained that this PACHA meeting would focus on Federal policies that affect all the social determinants of health, including housing and social justice. Ms. McNeese outlined President Joe Biden's budget request for fiscal year (FY) 2024, which proposes a new 5-year national program to eliminate hepatitis C and includes funding for *Ending the HIV Epidemic: A Plan for America* (EHE), a new national pre-exposure prophylaxis (PrEP) for HIV program, and SAMHSA harm reduction programs. It also proposes changes to increase access to health care insurance. However, the request proposes flat funding for a number of programs addressing HIV, opioid use disorders (OUDs), and sexually transmitted infections (STIs).

In honor of Women's History Month, Ms. McNeese recognized several public health trailblazers in the HIV community who died in the past year: Janet Cleveland; Dawn Smith, M.D.; and Ava Edwards. Ms. McNeese introduced a video produced for the HHS COVID-19 public education campaign We Can Do This highlighting the achievements of current PACHA member Ada Stewart, M.D., RPh, FAAFP, AAHIVS, HMDC, who has dedicated her career in medicine to serving the underserved and underrepresented.

Dr. Wiesman described PACHA's visits to three area community organizations to learn more about services on the front lines of HIV prevention and treatment: REACH Baltimore, Us Helping Us, and La Clinica del Pueblo. Each organization plays a vital role in the community but faces challenges around reimbursement and other policies. All three organizations can attest to the need for a comprehensive and holistic approach to HIV care.

Dr. Wiesman explained the role of PACHA and summarized the agenda for the meeting. (This meeting was broadcast live online; the recorded broadcast is available [online](#).) PACHA will meet next on June 27–29 in Arizona, September 19–20 virtually, and December 5–7 in Houston, TX.

### Roll Call

*B. Kaye Hayes, M.P.A., PACHA Executive Director; Director, OIDP; Deputy Assistant Secretary for Infectious Disease, OASH, HHS*

Ms. Hayes called the roll.

## Welcome from the Assistant Secretary for Health

*ADM Rachel L. Levine, M.D., Assistant Secretary for Health, HHS*

ADM Levine thanked the Council members for their thoughtful input and expertise as well as their individual efforts at the national and global levels to end HIV. She appreciated the opportunity to join the PACHA visits to some of the organizations representing the Washington, DC, area's vibrant HIV community. These site visits provide helpful insight on innovative ways to expand access to HIV services and improve outcomes for people with HIV and those at risk.

During its last meeting, PACHA passed a resolution calling for updated guidelines on blood donation deferral, and FDA has since released draft guidance to the industry on the matter. In addition, on World AIDS Day, ADM Levine announced that the USPHS Commissioned Corps was ending its medical exclusion for people with HIV and people with hepatitis B, making it the first of the uniformed services to do so.

ADM Levine outlined key items in President Biden's budget request to end HIV and hepatitis C, adding that other proposals complement EHE and the *National HIV/AIDS Strategy* (NHAS). For example, the proposed budget would reduce Medicaid costs by eliminating barriers to PrEP access for beneficiaries. It would also create a new mandatory program to guarantee PrEP at no cost for all uninsured and underinsured individuals; provide essential wraparound services through States, the IHS, Tribal entities, and localities; and establish a network of community providers to reach underserved areas and populations. ADM Levine said PACHA would receive an update at this meeting with the latest information on policies for molecular HIV surveillance (MHS) and cluster detection response (CDR), which are important public health tools. She appreciated PACHA's close attention to the safe and effective use of these tools.

ADM Levine noted that the wide range of Federal partners presenting at this meeting demonstrates the collective Federal commitment to reduce stigma, increase access to HIV services, and support syndemic approaches. Understanding syndemics—the clustering and interaction of two or more diseases as a result of social and structural determinants of health that lead to excess burden of disease in a population—is crucial. ADM Levine noted the alarming resurgence of syphilis across the United States, pointing out that untreated STIs can lead to long-term irreversible health outcomes and facilitate HIV transmission. Recognizing these links, HHS simultaneously developed the *STI National Strategic Plan* and the *Viral Hepatitis National Strategic Plan* alongside the updated NHAS in 2020. Countries around the world are facing the same challenges, as revealed during the Global and Domestic HIV Bidirectional Learning Forum at the 2022 International AIDS Conference, in which ADM Levine participated.

The Biden-Harris administration and HHS remain focused on addressing the Nation's substance use crisis. Since the release of the HHS Overdose Prevention Strategy, the Nation has expanded treatment capacity, saved lives from overdoses, improved access to harm reduction services, and increased commitment to long-term recovery supports. However, challenges remain. Although HIV incidence among people who inject drugs has declined substantially, the rising use of opioids and other substances threatens the success of HIV prevention efforts. ADM Levine appreciated PACHA attending to these issues, because the community must continue to explore how to better integrate treatment for HIV and substance misuse. On behalf of HHS Secretary Xavier Becerra and HHS, ADM Levine thanked the Council for its enduring commitment.



## White House Response to PACHA Resolution on MHS/CDR

*Harold J. Phillips, M.R.P., Director, ONAP*

Mr. Phillips acknowledged community concerns about MHS/CDR for HIV but emphasized that CDC uses these tools to target resources where they are most needed. CDC and other agencies have held numerous public meetings, webinars, and listening sessions to gather insights about MHS/CDR. In October 2022, PACHA passed a [resolution](#) reflecting community concerns. Mr. Phillips said MHS/CDR is a critical component of EHE, particularly for ensuring rapid treatment and disrupting transmission patterns. It helps identify gaps in services among marginalized people and therefore is a tool to address inequity. Mr. Phillips offered examples from [Detroit](#) and Atlanta demonstrating the use of MHS/CDR to pinpoint rapid HIV transmission within vulnerable populations and how those cities mobilized resources to meet community needs. He added that CDC is trying to better communicate the successful use of [MHS/CDR in the field](#).

Community involvement starts with the development of jurisdiction-specific CDR plans that are required by funding agreements. That planning must involve not only general community engagement but also input and participation from people with HIV. Mr. Phillips cited examples from Michigan and [San Antonio, TX](#), illustrating how advocates and people with HIV worked with public health officials to implement MHS/CDR in their communities.

Some of the recommendations in the PACHA resolution conflict with the goals of using MHS/CDR to support public health, Mr. Phillips stated. Specifically, not collecting data needed to identify and interrupt HIV outbreaks would neglect the public health mission and compromise health for many. Every effective tool available should be used to end the HIV epidemic. Furthermore, allowing individuals to opt out of sharing HIV data with the health department would result in insufficient data to inform how programs are built or resources allocated. It would also weaken the ability to justify the resources and programs needed to end HIV.

However, Mr. Phillips noted, efforts are being made across the country to protect molecular HIV data, modernize HIV criminalization laws, and ensure that MHS/CDR activities benefit the communities where they take place. CDC is incorporating components of PACHA's recommendations, such as provider education on communicating with patients about how public health data are used for surveillance. Furthermore, CDC already requires that individual consent be obtained before any HIV molecular data collected through the National HIV Surveillance System are added to a public repository. In response to input from partners that the requirements for implementing MHS/CDR are too rigid in some contexts, CDC is considering a more flexible framework that allows jurisdictions to tailor their use of these tools.

On the issue of strengthening data protections, CDC already requires consent and limits the use of data submitted to a public repository. It is updating NCHHSTP data security and confidentiality guidelines, which already limit data reporting to information that advances specific HIV prevention efforts. The updates include aligning information technology and security measures with the the latest technology and strengthening policies on release of data for public health purposes.

CDC cannot advocate for States to change their laws, but it can identify where State laws conflict with HIV science. The White House convened a forum on HIV criminalization in 2022,

and CDC clarified that some of its funding can be used for education around modernizing HIV criminalization laws. CDC launched the [HIV Criminalization Legal and Policy Assessment Tool](#), and the Minority HIV/AIDS Fund (MHAF) is supporting a learning collaboration of States around use of this tool. Mr. Phillips emphasized that the overall goal is to foster partnership among public health and criminal justice professionals, legislative systems, and policymakers to ensure that HIV-related laws are based on evidence and support public health. CDC is also educating providers on data use for public health and building a clearinghouse of information and peer-reviewed evidence on CDR.

Mr. Phillips said other PACHA suggestions are under consideration. He emphasized that surveillance is the backbone of public health. Collection and analysis of molecular data are critical to ensuring that resources for HIV prevention and care reach those who need them. Effective and appropriate CDR efforts require strong partnerships across Federal entities and with State and local agencies.

## **Federal Updates on EHE Activities**

### **CMS Update**

*Lee A. Fleisher, M.D., Chief Medical Officer and Director, Center for Clinical Standards and Quality, CMS*

In addition to its role as a payer, CMS has many levers to influence the quality of and access to health care, including regulations, clinical standards, and quality improvement incentives, said Dr. Fleisher. Coverage of HIV services is complicated by Federal and State statutes dictating what Medicare, Medicaid, and private insurers who participate in the Affordable Care Act (ACA) marketplace can cover. CMS expects to release a national coverage determination about PrEP in July, based on positive analysis by the U.S. Preventive Services Task Force (USPSTF) and others about its effectiveness. The determination will be open for public comment, and Dr. Fleisher assured the participants that CMS carefully reviews and considers all public comments.

CMS' National Quality Strategy seeks to advance equitable, whole-person-centered care that prioritizes community engagement, safety, and resiliency while striving to improve outcomes, interoperability, and incorporation of scientific advancements. The strategy aims to enhance alignment across programs and settings; to this end, CMS has proposed a universal foundation for measuring outcomes. Dr. Fleisher welcomed input on what measures should be addressed. CMS is also adapting its merit-based incentive payment system (MIPS), which measures performance of individual clinicians, for the MIPS Value Pathways program, which assesses the performance of the care team as a whole. Both programs promote accountability.

When mpox emerged, representatives of public and commercial payers met frequently to navigate the complex coverage systems for vaccines, screening, and treatment. Medicaid policies varied substantially across States, raising questions about ensuring coverage that is not State-dependent and also available through commercial plans. Dr. Fleisher presented some examples of cooperation across Federal agencies to support HIV programs, many of which focus on closing gaps in equity and reaching the underserved.

## **HUD Office of HIV/AIDS Housing Updates**

*Rita Harcrow, Director, Office of HIV/AIDS and Housing, HUD*

Ms. Harcrow noted that HUD's Housing Opportunities for Persons with AIDS (HOPWA) program recently celebrated its 30<sup>th</sup> anniversary. In December 2021, HUD awarded 20 new grants totaling \$40 million through its Housing as an Intervention to Fight AIDS (HIFA) program, the first new competitive HOPWA funding opportunity in 5 years. It aligns with EHE and incentivizes HOPWA grantees to collaborate with EHE-funded partners. HIFA is expected to provide the first health outcome measures directly related to HOPWA housing.

HOPWA received \$65 million in supplemental funding for its COVID-19 pandemic response. Some of the regulatory waivers granted to HOPWA during the pandemic will become permanent changes, such as allowing virtual home inspections for ongoing rental assistance. Ms. Harcrow said that for years HOPWA has repeatedly asked that the time caps on short-term rental assistance be extended, and she hoped that the evidence gathered during the pandemic would support that request. In the wake of mpox, which affected people with HIV and unhoused people most severely, HUD notified Congress about the need for stable housing to get people with HIV reconnected to services. The President's FY 2024 budget proposed a \$6 million funding increase for HUD, which would enable HOPWA to provide access to affordable housing for 48,000 people with HIV and their families and other supportive services to ensure that 65,000 people have stable housing.

HUD is supporting NHAS implementation through its offices on public housing, Indian housing, and special needs. HUD is collaborating with CDC, HRSA, and SAMHSA and hopes to create more opportunities for local communities to build on those Federal efforts.

## **NHAS, EHE, and the MHAF**

*Timothy Harrison, Ph.D., Principal Deputy Director, ODP, HHS*

Dr. Harrison explained that ODP promotes collaboration and stakeholder engagement in EHE. It uses MHAF to support various EHE efforts (e.g., workforce training, capacity-building, technical assistance, and status-neutral and syndemic approaches to care), maintain America's HIV Epidemic Analysis Dashboard (AHEAD), and embed Prevention through Active Community Engagement (PACE) program officers in regions key to EHE. ODP also develops national public awareness campaigns, such as [I Am a Work of ART](#). With the ACL, ODP launched the HIV and Aging Challenge prize competition to fund innovative, community-developed approaches to address nonmedical needs of people aging with HIV. Dr. Harrison said ODP seeks to initiate some campaigns raising awareness about issues facing young people with HIV.

ODP convened a Syndemic Steering Committee to address HIV, STIs, hepatitis, substance use disorders (SUDs), and mental health challenges. The committee is moving Federal agencies toward standardized language and guidance on topics such as blending funding to implement syndemic approaches. ODP is also leading a project to gather best practices, challenges, and lessons learned from U.S. programs that have enacted successful approaches to treating syndemics. Dr. Harrison pointed out that ONAP and ODP coordinated the development of four key national strategic plans to facilitate an integrated approach to addressing HIV/AIDS, hepatitis, STIs, and vaccines. These strategies are a reminder that the collective response to HIV

must consider the syndemic, address upstream social and structural barriers that confound the best biomedical strategies, and be person-centered, Dr. Harrison concluded.

### **HRSA HIV/AIDS Bureau Updates on EHE**

*Heather Hauck, M.S.W., LICSW, Deputy Associate Administrator, HIV/AIDS Bureau, HRSA*

Ms. Hauck summarized FY 2023 HRSA HIV/AIDS Bureau funding for EHE recipients, noting that additional awards are expected later in 2023 to expand the HIV workforce through the Ryan White HIV/AIDS Program AIDS Education and Training Centers (AETCs). Some EHE-funded jurisdictions overlap with current Ryan White program sites, allowing the jurisdictions to leverage systems in place. In 2020, EHE recipients exceeded the year 1 goal of reaching 18,000 clients (new or reengaged), despite the fact that State and local health departments deployed most clinicians to address the COVID-19 pandemic.

The EHE initiative encouraged recipients to be innovative. Although COVID-19 posed many unexpected barriers, jurisdictions used the opportunity to expand Ryan White program services through technologic and structural changes, such as offering telehealth visits, which proved to be popular with clinicians and clients. Recipients also used mobile vans to expand services and created one-stop service models. The initiative also spurred new and expanded partnerships, demonstrating how jurisdictions identified and met needs of their communities. With EHE funding, the HRSA HIV/AIDS Bureau leveraged AETCs' capacity for workforce training and technical assistance, linking AETCs with State and local health departments. The AETCs launched a new HIV prevention provider training program, a community health worker advisory group, and new communities of practice. Ms. Hauck pointed out that community engagement is a hallmark of the Ryan White program, and that legacy has carried over to the EHE initiative with numerous listening sessions to gather feedback. She anticipated continued joint CDC and HRSA listening sessions across the country about EHE and related topics to better understand the challenges communities face and what works.

### **IHS Update**

*Rick Haverkate, M.P.H., National HIV/AIDS & Hepatitis C Program Coordinator, IHS*

Mr. Haverkate summarized the *Indigenous HIV/AIDS Syndemic Strategy* (Indigi-HAS), which builds on the NHAS and the national strategies on STIs and hepatitis and applies the lens of indigenous people's health. The result is a guide that IHS constituents can use to develop their own policies and practices. Indigi-HAS aligns with the four pillars of EHE—diagnosis, treatment, prevention, and response—and adapts the vision of the NHAS to reflect indigenous values. It emphasizes a holistic approach to care that encompasses the spirit, body, mind, and relationship with the land. Indigi-HAS also recognizes core values common across indigenous communities, such as the strength of the community, interconnectedness, diversity, and balance.

Indigi-HAS aims to align goals and strategies across the three national plans and inform communities about promising programs and practices. It offers indicators for measuring progress. Indigi-HAS is organized around six main messages:

- Sovereignty: Center indigenous sovereignty in the design and delivery of health services, including sexual health services.

- Cultural responsiveness: Deliver culturally and linguistically responsive health services, including sexual health services.
- Partnerships: Strengthen partnerships to improve systems of care for indigenous people.
- Awareness and stigma: Reduce sexual health-related stigma.
- Availability and capacity: Develop capacity to support diagnosis, treatment, prevention, and response to HIV, STIs, and viral hepatitis.
- Data systems: Improve the knowledge, evidence, and practice base related to indigenous health and well-being.

## Discussion

Mr. Schmid suggested that PACHA have liaisons representing each facet of CMS—Medicare, Medicaid, and the ACA marketplace, all of which are heavily involved with the EHE initiative. Dr. Fleisher agreed, adding that the current administration is focused on improving coordination across all programs and determining what CMS can achieve within its statutory authority. Ms. McNeese raised concerns about local health plan coverage determinations in Texas that would prevent coverage of a single-tablet regimen for treating HIV. Dr. Fleisher responded that CMS will review such rules, especially those that affect health equity.

CMS is reviewing waivers enacted during the public health emergency (PHE); for example, it will extend waivers allowing the use of telehealth across State lines. However, Dr. Fleisher noted, CMS has limited authority, and medical practice is regulated by States. He urged PACHA to raise its concerns to the President. Ms. Harcrow added that HUD is also seeking to make permanent some of the temporary waivers granted during the PHE. Ms. Hauck commented that EHE funding gave many HRSA awardees more flexibility to try new approaches, and HRSA wants others to learn from best practices. HRSA strongly encourages more attention to flexibility around determining eligibility and facilitating enrollment (e.g., using online technology). Dr. Fleisher noted that a number of people will be dropped from Medicaid programs when the PHE officially ends but are eligible for marketplace subsidies, and he welcomed input on how to help individuals re-enroll.

Justin C. Smith, M.S., M.P.H., stated that siloed funding prevents grantees from putting a status-neutral approach into practice. He appreciated the Syndemic Steering Committee's attention to blending and braiding funding. Dr. Harrison said the Committee is working toward a common understanding of the syndemic across agencies and figuring out how to focus efforts to address it. He agreed that the siloes around funding are challenging. The EHE initiative has provided more flexibility to awardees, which has helped facilitate consideration across agencies.

## Federal Updates on EHE Activities (continued)

### NIH OAR Update

*RDML Timothy H. Holtz, M.D., M.P.H., FACP, FACPM, USPHS, Deputy Director, OAR, NIH*

Overall NIH research funding has increased steadily since 2018. The bulk of NIH's role in EHE is supporting implementation research to better understand how to adapt interventions for different geographic and cultural contexts. Dr. Holtz presented data depicting the number of NIH projects by population, with a focus on populations disproportionately affected by HIV. Through supplemental funding, NIH has supported a wide range of HIV research topics. In FY 2023, it

will focus funding on syndemic approaches, leveraging pharmacies, linking people to care following incarceration, and cluster detection.

NIH received \$26 million for EHE-related research for FY 2023; a portion of that amount will go toward projects under way that emphasized approaches to improve health equity, and most will support projects that aim to bridge the gap between research and practice, primarily through Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs). Since EHE began, NIH has established a research footprint in 52 of the 57 jurisdictions. The research conducted by CFARs and ARCs involves health care organizations; State and local governments, including health departments, Tribal governments, and correctional facilities; community-based organizations (CBOs) serving various special populations; and nontraditional and academic partners, including faith-based organizations and small businesses. Thanks to connections with more than 400 community partners, the work of CFARs and ARCs is amplified broadly.

One example of NIH collaboration with Federal partners is the 2022 special issue of the *American Journal of Public Health*, which described research and U.S. government efforts to address intersectional stigma and discrimination to improve HIV-related outcomes. NIH also has two active funding opportunities on stigma that were informed by previous research.

### **BPHC Update**

*Ernia P. Hughes, M.B.A., Director, Office of Health Center Investment Oversight, BPHC, HRSA*

Ms. Hughes said HRSA's health centers provide primary care and services to 32 million people across the United States, making them a crucial component of EHE. Since 2020, HRSA has increased the number of health centers engaged in EHE each year, resulting in a growing cohort of centers with the resources to provide competent care and capacity to share best practices. This approach enables HRSA to realize the priority of health equity.

HRSA health centers focus heavily on HIV prevention as well as treatment. With EHE funds, health centers have conducted 1.7 million HIV tests, offered PrEP to more than 50,000 people, and linked 86 percent of newly diagnosed people to care within 30 days. Ms. Hughes emphasized that these figures represent a solid base, but there is much more work to do. Over the past 3 years, health centers have faced significant challenges addressing HIV at the same time as COVID-19, but the commitment of HRSA and its health centers endures.

Health centers' reach extends beyond the EHE jurisdictions. Of the 1,400 U.S. health centers, 958 provide PrEP and other HIV services. Health centers are leading the way in gender-affirming care and in recognizing the syndemic. They embody the concept of the medical home that provides whole-person care. HRSA also invests in partnerships at the local level, to fill gaps in service. The agency created a specialized team to work with health centers that receive Primary Care HIV Prevention funding. It also assists health centers through the Health Information Technology Training and Technical Assistance Center and its AETCs. HRSA maintains strong partnerships through primary care associations and the National Association of Community Health Centers.

## **CDC Update**

*Robyn Neblett-Fanfair, M.D., M.P.H., Principal Deputy Director, NCHHSTP, CDC*

Dr. Neblett-Fanfair explained that two CDC funding opportunities are ending in May 2024 as part of an effort by CDC to streamline the grant process, reduce burden on future grantees, and minimize the impact of continuing resolutions. The President's proposed FY 2024 budget would increase CDC's EHE funding, but even with level funding, Dr. Neblett-Fanfair anticipated that health departments would receive at least as much funding as in FY 2023.

In 2021, health departments in EHE jurisdictions made significant progress in HIV testing and linking people to care. Self-testing ramped up during COVID-19, with CDC distributing 100,000 free tests and grantees distributing another 16,000 self-test kits locally. CDC grantees linked 84 percent of newly diagnosed people to care within 30 days, and three jurisdictions met the 2025 goal of 95 percent. Five jurisdictions met the 2025 goal of prescribing PrEP to at least 50 percent of those deemed eligible. In addition, EHE funded some STI specialty clinics and syringe service programs, which are identifying and linking more people to PrEP.

In February 2021, the Georgia Department of Public Health detected four clusters consistent with recent and rapid HIV transmission. A rapid qualitative assessment, conducted by public health entities with input from CBOs and provider organizations, found the outbreak was related to low awareness of HIV and STI services and to structural barriers, such as fear of deportation, problems with transportation, and work and family responsibilities. Recommendations emphasized the critical nature of building partnerships and developing services that are trusted and linguistically appropriate and reach people where they are.

CDC is committed to meaningful, ongoing community engagement at all levels and will join HRSA in combined listening sessions this summer. Some themes identified already include the need to break down funding silos and promote collaborative work; increase and diversify the public health workforce; ensure the public health workforce earns a living wage; expand HIV testing in various facilities; increase focus on housing, employment, and mental health services; and go beyond the biomedical model to consider the whole person.

Dr. Neblett-Fanfair highlighted some new CDC funding opportunities, including one seeking to increase PrEP use among Black, cisgender women; one to identify ART preferences among Black women; and another to identify the historic and structural drivers of medical mistrust among Hispanic and Latino men who have sex with men. CDC will maintain focus on the four pillars of EHE with key strategies to advance health equity, including self-testing, syndemic approaches, building local capacity, increasing PrEP access, and reducing stigma.

## **SAMHSA Update**

*Kristin Roha, M.S., M.P.H., Public Health Advisor for HIV, SAMHSA*

In November 2022, SAMHSA updated its mission, emphasizing its support for treatment and recovery while ensuring equitable access and better outcomes. Ms. Roha gave an update on SAMHSA's Substance Abuse Prevention and Treatment block grant, which includes some funding for HIV intervention in States with 10 or more AIDS cases per 100,000 individuals. Because the definition has not been updated, only two States are eligible in 2023. In FY 2022,

SAMHSA began providing additional points to EHE jurisdictions applying for its Minority AIDS Initiative grant programs, increasing the number of EHE jurisdictions among awardees.

SAMHSA's Minority AIDS Initiative grant for high-risk populations seeks to increase engagement in care for people who are medically underserved (on the basis of race or ethnicity); have SUDs, mental health conditions, or both; and are at risk for or are living with HIV.

Grantees are eligible for up to \$500,000 per year for 5 years. SAMHSA aims to provide at least five awards to American Indian and Alaska Native (AI/AN) Tribes or Tribal organizations in 2023. The grant's new requirements highlight evidence-based approaches (such as postexposure prophylaxis and communicating that when HIV levels are undetectable, the virus cannot be transmitted [undetectable equals untransmittable, or U=U]); improving cultural awareness and responsiveness; and enhancing diversity, equity, inclusion, and accessibility.

The Treatment for Individuals Experiencing Homelessness grant seeks to provide comprehensive, coordinated, and evidenced-based services for people with mental illness who are homeless or are at imminent risk of homelessness. Beginning with the 2023 cohort, grantees can use their funding to implement outreach and education strategies for HIV and hepatitis screening; refer participants to treatment and prevention services; and follow up on the provision of services. Through previous SAMHSA grants, cohorts are supporting prevention navigators who educate about substance misuse and HIV, service integration that addresses the syndemic, and harm reduction services.

## **ACL Update**

*Edwin Walker, J.D., Deputy Assistant Secretary for Aging, ACL*

Mr. Walker explained that ACL is supporting NHAS implementation by formally and informally evaluating the capacity and competency of its network to serve aging people with HIV. For example, people with HIV are included in this year's National Survey of Older Americans Participants, which provides demographic information that illuminates how services are used and by whom. ACL has increased its focus on HIV in current programs, such as updating the Self-Management Resource Center's Positive Self-Management Program, providing continued funding for various national minority resource centers, and supporting the National LGBTQI+ Resource Center at SAGE. In 2021, ACL updated guidance to States on developing their plans for providing aging services; it now includes more detail on target populations and requires State plans to indicate how they will serve older people with HIV. In the first batch of plans sent to the ACL since the updated guidance came out, States have indicated they will increase coordination and improve service integration between government agencies and service providers. ACL is launching technical assistance to further aid States with planning.

ACL is partnering with OIDP on two prize competitions of \$500,000 each that call for innovative approaches to serving older people with HIV, with support from the MHAF. The challenge prizes focus on racial and ethnic minorities and LGBTQI+ populations disproportionately affected by HIV. The challenges will specifically target aspects that improve the quality of life, as identified by people with HIV, such as social connectedness, wellness, nutrition, and psychosocial support. Within HHS, ACL is collaborating with CMS on coverage of PrEP, with HUD on a webinar for HOPWA grantees, and with HRSA on a Ryan White Special Projects of National Significance initiative on HIV and aging as well as the annual Ryan White conference.



## Discussion

Regarding the use of research about aging people with HIV, Mr. Walker said that ACL gathers information from its own programs as well as data from clinical research and translates them into practical interventions that can be implemented by CBOs. For example, ACL's chronic disease self-management courses rely on the best data from NIH's National Institute on Aging. Dr. Holtz noted that NIH has an active working group on HIV and aging, coordinated by OAR and NIH, that informs the work of multiple NIH Institutes and Centers. He hoped such work would expand beyond NIH, given that a significant portion of people with HIV are over age 50.

Dr. Neblett-Fanfair emphasized the community engagement that took place in Atlanta around the use of MHS/CDR that identified a rapid transmission of HIV. More details will be published online soon, which Dr. Neblett-Fanfair hoped would offer a blueprint for investigations of outbreaks. Regarding CDC's thinking about the structure of a national PrEP program, Dr. Neblett-Fanfair said that an analysis by the late Dr. Dawn Smith on unmet needs around PrEP and financial implications will likely inform the discussion.

Mr. Phillips commented that HOPWA and the Ryan White program have updated their eligibility requirements over the years to reflect the burden of HIV rather than the number of AIDS cases. Therefore, it is hoped that SAMHSA's outdated criteria for eligibility will be addressed through a focus on modernization. If the SAMHSA criteria used HIV cases, at least 20 States would qualify for the HIV set-aside funds in the block grant (on the basis of data from 2022).

Ms. McNeese appreciated that the presentations from the Federal partners demonstrated their intention to collaborate, although there is much more to do. Mr. Phillips said efforts are under way to collect information and data about EHE successes and challenges and make it more readily available so that advocates can use it in support of requests for EHE funding.

PACHA members requested the following data from presenters:

- BPHC: Number of eligible health center clients who are taking PrEP and demographic data on PrEP users
- NIH: Demographic analysis of principal investigators on OAR research projects at minority-serving ARCs and historically Black colleges and universities
- NIH: Budgets of the projects that OAR funds serving various populations disproportionately affected by HIV (to clarify the actual resources dedicated to specific populations)

## Update from the President's Emergency Plan for AIDS Relief (PEPFAR)

*Mamadi Yilla, Ph.D., Deputy Coordinator, Multisector Relations, Office of the U.S. Global HIV/AIDS Coordinator, U.S. Department of State*

Dr. Yilla emphasized that PEPFAR's success stems from being mission-driven; focusing on accountability, transparency, equity, and impact, and maintaining an enduring relationship with the populations it was created to serve. The program is celebrating its 20<sup>th</sup> year and has had support of President Biden since his time in Congress. PEPFAR has achieved "spectacular" health and development outcomes, helping to save 25 million lives. Secretary of State Antony

Blinken released a new PEPFAR 5-year strategy in December 2022 and announced the intention to elevate attention to global health security and global health diplomacy through the ongoing work of PEPFAR by creating a new bureau at the Department of State. The new strategy focuses on the unfinished work to end HIV/AIDS as a public health threat by 2030 and learn from the lessons of the COVID-19 pandemic. It seeks to sustainably strengthen public health systems, the health workforce, procurement and supply systems, laboratory networks, and information systems needed to address HIV/AIDS in resource-constrained environments.

PEPFAR's strength has been its focus on data. Current data indicate that adolescent girls continue to bear the brunt of new infections; that barriers persist in serving children; and that interventions are not reaching key populations, particularly men who have sex with men and transgender communities. Health equity is central to PEPFAR's strategy, and it is working on approaches that are easy to implement, such as combining prevention and intervention and incentivizing local innovations. Strengthening national and regional health institutions remains a high priority. The new strategy aims to incentivize regional manufacturing; with the Global Fund, PEPFAR seeks to advance regulatory mechanisms and mobilize non-U.S. financing to accelerate manufacturing of HIV diagnostics. PEPFAR emphasizes a multisectoral approach.

Ultimately, civil society organizations keep PEPFAR and the governments of countries with which it partners accountable. More than 1,300 people attended PEPFAR's operational planning meeting in Johannesburg, South Africa, over a 2-week period. Data show that PEPFAR is not fully meeting the needs of young people. Dr. Yilla said that PEPFAR was transformed by the youth who seized the moment in Johannesburg, making it clear they wanted to be involved in solutions and be an equal partner at the table so that yet another generation will not be lost to HIV/AIDS.

## **Discussion**

Dr. Yilla observed that, as an invited guest in other countries, PEPFAR faces a singular challenge to move the agenda around stigma facing gay and bisexual men and transgender women in particular. The COVID-19 pandemic demonstrated that the United States has not gotten everything right at home. But the United States still has influence and can bring people to the table. PEPFAR's new strategy highlights the structural barriers to progress. However, PEPFAR cannot apply a blunt instrument to advance its goals; programs must be tailored to serve the needs of diverse populations. In some cases, attention can make an environment unsafe for the populations that PEPFAR serves.

PEPFAR has an advantage in data collection because it built programs and created a relatively permissive environment that allows it to gather and compare information. A core characteristic of PEPFAR has been its ability to report disaggregated data in detail, which has helped it secure resources, and partners understand that. Partners capture a lot of information about orphans and vulnerable children, which they report to PEPFAR and are now reporting to their own ministries. Dr. Yilla emphasized that data do not lie. Organizations such as PEPFAR cannot be afraid of learning the truth. Having good information is crucial to making the case for programs, and that lesson is just as important for domestic HIV programs as international ones.

## **Addressing Stigma Through Bidirectional Learning: Global and Domestic Perspectives**

*Jennifer Kates, Ph.D., and Justin C. Smith, M.S., M.P.H., PACHA Members, Co-Facilitators*

Mr. Smith stated that a biomedical approach to treating HIV will not fully succeed as long as stigma persists. Dr. Kates cited examples of institutionalized stigma. She noted that HHS and ONAP have encouraged bidirectional learning to share lessons learned.

### **Fighting Stigma at the Local Level**

*Katie Conner, M.P.H., Director of HIV Services, CrescentCare, New Orleans, LA*

Ms. Conner described many logistic steps taken by CrescentCare to minimize stigma, including changing its name, moving to a new location, and becoming a Federally Qualified Health Center (FQHC) that offers a wide range of care alongside HIV services. It has hired members of the local LGBTQI+ community to conduct outreach that emphasizes HIV prevention. CrescentCare is a safe haven for gender-affirming care; it hired more providers to meet the growing demand for such care, including three with transgender experience, and offers legal assistance to help transgender people navigate the process of changing their names. CrescentCare's syringe services program offers clean syringes as well as medication to treat overdoses, COVID-19 vaccine, and assistance with Medicaid enrollment.

CrescentCare offers rapid HIV treatment for all newly diagnosed people, because delaying care initiation can make people feel as though they are being dismissed and providers' efforts to "assess readiness" to begin care are a source of bias. The organization emphasizes U=U, which helps reduce fear among those newly diagnosed with HIV. Ms. Conner said CrescentCare is now focusing on dismantling HIV criminalization laws and advocating for increasing the number of women in HIV clinical trials to ensure more equitable care.

### **MPX NYC: Community-Led Response to Mpox in New York City**

*Keletso Makofane, Ph.D., M.P.H., Health and Human Rights Fellow, François-Xavier Bagnoud Center for Health and Human Rights, Harvard University*

Dr. Makofane described novel approaches to coordinate an informed response to mpox in an environment where tests and vaccines were limited and outreach and testing were not effectively identifying those at highest risk, particularly people who engage in group sex. By consulting with their friends and families, Dr. Makofane and colleagues soon learned there was no forum for talking about mpox and only limited understanding of how people negotiate online for sex. Their study, MPX NYC, became a mechanism for coordinating dozens of people who wanted to help address mpox in New York City, who then began working individually or collaboratively. The coordination led to creation of an mpox vaccine locator website, policy briefs for city and State health department leaders, and guidance on safer sex. Most notably, MPX NYC used information provided by study participants about where they were having group sex, while preserving individual anonymity. The resulting data enabled local response teams to target efforts in places where people were having a lot of group sex. Having detailed, location-specific data directly influenced decision making and response in the midst of the mpox outbreak.

Dr. Makofane outlined the framework of a successful research-based intervention, noting that the approach is rooted in the work of civil society organizations and health programs globally:

- Consultation in a community forum, giving people opportunity and power to make decisions, not just give input
- Rapid mobilization of resources for response, including standing up research quickly
- Surveillance in the community, not just in clinical settings
- Coordination across organizations and settings
- Communication that is sex-positive and makes recommended options clear

## **Addressing Stigma and Discrimination in PEPFAR's Programs**

*William Miller, Ph.D., Senior Key Populations Advisor, Office of the U.S. Global AIDS Coordinator, U.S. Department of State*

Dr. Miller explained that in addition to the targets outlined in PEPFAR's 5-year strategy, PEPFAR will lead the way toward reaching the UNAIDS Global AIDS Strategy's targets for removing legal barriers, gender inequality, stigma, discrimination, and violence that prevent access to or use of HIV services. In its 2023 guidance for country and regional operations planning, PEPFAR provided new information on the structural barriers to achieving those targets. At a minimum, planning must advance human rights and decriminalization for LGBTQI+ people, plan and budget for health care worker sensitization and training on reducing stigma, and address violence and human rights violations experienced by key populations.

PEPFAR's guidance emphasizes that in-country teams should gather information from individuals on specific barriers to care. Such community-led monitoring in [South Africa](#) determined that people did not access care because facilities lacked privacy, safety, and friendly services for key populations. The [People Living with HIV Stigma Index](#) offers tools for collecting data to better understand stigma. Dr. Miller described PEPFAR resources for gender and sexual diversity training, which can be conducted virtually or in person. Such training is available for general public health and clinical facilities as well as for centers offering specialized care, such as hormone therapy. Other tools include key population competency assessments, a self-assessment exercise for partners implementing programs, and a competence assessment from Namibia's Positive Vibes.

## **Moving Toward Accountability**

*Tonia Poteat, Ph.D., M.P.H., PA-C, Associate Professor of Social Medicine, University of North Carolina, Chapel Hill*

Dr. Poteat appreciated PEPFAR's focus on data, but urged the group not to forget the people behind the data, and particularly the appalling treatment some have experienced in the context of seeking care, ranging from insults to rape. The goal is not only to increase access to care or end HIV but also to ensure that everyone enjoys the human rights they deserve. PEPFAR's gender and diversity training includes presenters who describe their own experiences with stigma and discrimination, and it has had a meaningful impact on participants.

Dr. Poteat emphasized that research should be community-led but also have an impact on the community. Once interventions are identified as effective, it is not enough to share the information. Where there is access to power and money that can make a difference, there is an obligation to implement those interventions. In the United States, the EHE initiative is an opportunity to bring money and power to bear on the problem of stigma. Federally funded organizations should be held accountable for implementing interventions that work.

Finally, Dr. Poteat said it is important to listen to and be led by people most affected by stigma and discrimination. She appreciated resources such as the People Living with HIV Stigma Index, which provides great information on individual experiences, and reiterated the need to hold organizations accountable for implementing what works.

## **Questions and Answers**

### ***What key principles or best practices are central to addressing HIV stigma?***

Dr. Makofane said queer and transgender people understand the problems in health programs and policies, and their concerns should be taken seriously. Every community has lessons to offer. In Kenya, for example, a united approach across civil society to address the health of queer and transgender people led to policy changes. Dr. Poteat added that many domestic responses focus on helping people build resilience and create support systems, which is essential, but addressing the roots of stigma and discrimination is vital. In the United States, NIH supported an intervention to address structural racism and discrimination in Ryan White clinics, which mirrors what has been happening internationally.

Ms. Conner noted that CrescentCare staff members established an advisory council on transgender issues, generating a formal mechanism for bringing concerns to the leadership. In response to the advisory council, CrescentCare revised its electronic medical records to highlight the client's preferred name so that staff at all levels could be more welcoming. That effort also spurred CrescentCare to update its sexual orientation and gender identity (SOGI) data collection.

Dr. Miller echoed the importance of listening to the population served and including representatives of the key populations in designing and implementing programs, providing services, and monitoring progress. PEPFAR hopes to support more organizations led by and working for queer and transgender people.

Dr. Makofane pointed to the tendency to see stigma and discrimination in other countries but not in the United States, which provides legal protections for LGBTQI+ people. U.S. health care institutions may purport to give adequate information to clinical providers, but stigma persists.

### ***How can U.S. agencies support interventions that address stigma and discrimination?***

Dr. Poteat said that advocacy from within government agencies is influential. During her time with PEPFAR, she sought to increase visibility of transgender people and make a visible commitment to the community and advocates to represent their views internally. In addition, country teams must implement programs for key populations in a way that does not perpetuate stigma, so listening to their own communities is critical.

### ***How does CrescentCare's legal clinic assist with name changes for transgender people?***

Ms. Conner described the clinic, which relies on volunteers from CrescentCare's legal department. She added that local advocates succeeded in changing the city's court policies, substantially lowering the costs of filing the name change paperwork.

***Are the results of community-led monitoring shared with the people who provided information?***

Dr. Miller said the results are shared with the U.S. government agencies that implement programs. There is a gradual push under way to share the findings with ministries of health and the facilities that provide care. Dr. Miller said some reports are published and distributed, but PEPFAR can do better with getting results back to the communities served.

***How did CrescentCare's transgender advisory council start?***

Ms. Conner said staff at CrescentCare were inspired by the example of others who started a Black leadership advisory council. The council has since grown and joined with other advocates in New Orleans to form an independent entity that offers training, advocacy, and consultation services.

***What works to convince organizations to address structural racism?***

Dr. Makofane said structural racism is a political problem that requires political organizing. Listening to the community without dismissing their ideas as radical is one step that those within the bureaucracy can take. There must also be activists from the outside who hold decision makers accountable. Dr. Kates added that in some cases local organizations can implement creative solutions to overcome structural barriers that health care systems, States, or countries cannot. Dr. Poteat said communities can and do build their own alternatives, which are sometimes adopted into larger structures, such as free lunch programs at public schools, a concept initiated by the Black Panther party.

Dr. Poteat observed that engagement with law enforcement and incarceration is a huge driver of HIV. Thus, another approach to dismantling structural racism is creating alternatives to police response, such as unarmed responders. Vincent Guillamo-Ramos, Ph.D., M.P.H., LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN, added that PACHA should consider new ways to address the role of racism in HIV.

***What specific actions are effective to overcome internalized stigma as a barrier to care?***

Dr. Makofane said the materials developed from his study use language that mirrors how people talk about sex, particularly group sex, in a way that is respectful and normalizing. In communicating about his work, he makes a point of carefully considering language that might trigger negative responses. Mr. Smith added that hearing from individuals who are telling their own stories can help others be honest and transparent about their own experiences. Public health professionals can combat internal stigma by ensuring that colleagues have accurate information that they can disseminate in the context of authentic storytelling.

***What practices work at the highest levels of government to combat stigma when discrimination is legislated and institutionalized?***

Dr. Makofane noted that people build their own protective sanctuaries in even the most difficult environments. Many in the United States have weathered difficult political environments before. Activists have always found a way to mobilize within the system. Dr. Miller agreed, noting that the United States cannot tell countries to change their laws, but PEPFAR and other agencies can create space for progress to occur. The process is slow, and sometimes moves backward. PEPFAR must carefully navigate how it uses its power, money, and diplomatic resources to push

for change without setting off a backlash. Fostering growth from within is key. Dr. Poteat added that taking the long view of history is encouraging, and the United States can draw on examples from its own past to tackle current challenges.

Mr. Phillips noted that PEPFAR's latest 5-year strategy is better aligned with the NHAS than ever before. The NHAS also addresses racism as a public health threat. Mr. Phillips said that the U.S. government has taken an all-encompassing approach to HIV policy that treats all the States as single entity. Current events highlight States' differences, so the approach may need to be reconsidered. In addition, the Federal government must find more ways to support dialogue with civil society groups at the local and State levels around issues such as equity and inclusion.

### ***What else can the U.S. government do to address stigma in a sustainable way?***

Dr. Makofane suggested building collaborative structures among government and civil society organizations that are not dominated by government. He also proposed improving health communications to ensure that published products are attractive and engaging and use current and relevant language. Dr. Makofane said LGBTQI+ advocates in countries such as Uganda and Zimbabwe have a lot of great thinking to offer on difficult issues.

Ms. Conner said her community always needs more support for housing. She also suggested holding funded organizations accountable for implementing rapid initiation of HIV treatment, which is an effective, straightforward clinical intervention that can circumvent bias, along with direct linkage to care for people newly diagnosed with HIV. Ms. Connor added that Medicaid expansion was an important step for Louisiana, and anything that increases access to health care coverage can make a big difference in eliminating inequities.

Dr. Poteat stated that health care systems should be required to enact mechanisms to prevent stigma, just as they are required to meet other standards of care. One criteria for accountability might be whether a facility collects SOGI data. Another might be ranking facilities according to patient satisfaction data from LGBTQI+ people. Any efforts should be structured to outlive a single administration or special initiative. Dr. Poteat noted that the biggest barriers to care are often structural, such as financial barriers, distance from care, transportation options, and housing. Dr. Miller agreed that tackling structural barriers will lead to better health outcomes.

## **Public Comment**

**Shekinah Rose, a Positively Trans national board member**, said Black transgender women face the highest rates of homicide and acquired HIV diagnosis. Black transgender lives matter, sex workers' lives matter, people who inject drugs' lives matter, humans sexually trafficked lives matter, transgender immigrants' lives matter. The intersection of these is MHS. Mx. Rose said that sexual health education is key to empowering transgender youth to become proactive in their sexual health. Youth need to be educated about how to use drugs safely. More funding is needed for residential treatment in safe places for people to recover. Youth transgender men need education about their bodies and reproductive health. Transgender people need more education on what pregnancy looks like, what constitutes consent, how to draw boundaries with partners, and what body autonomy means. Current anti-transgender bills and laws aimed at transgender youth who are transitioning are creating child refugees across America. Providing transgender youth with the tools to succeed is a responsibility. Mx. Rose advocated for bringing back HIV

and STI prevention education in schools. They questioned whether providers tell patients why they are collecting SOGI data with their patients, how these data are used and stored, and who has access to the data outside of a provider's office. Every organization should have a transgender person who reviews the processing of SOGI data. Mx. Rose said pharmaceutical companies should be held accountable for including more cisgender women and transgender women and men in research, particularly clinical drug trial programs. Transgender men are hurting, because they lack choices and options. Mx. Rose said they are disgusted with the prospect of aged care, given their HIV/AIDS diagnosis, physical disabilities, mental health challenges, and the presence of bias, stigma, discrimination, transphobia, and hate. They said they see suicide happening a lot. Mx. Rose called for dignity and respect and for uprooting and changing aged care.

**Doug Rose, an HIV/AIDS advocate from Baltimore**, raised concern about MHS. He expressed discomfort with the idea that, without informing the patient, a doctor can submit blood samples to a laboratory, which then sends the results to the Health Department, which uses the information to try to find other people in the patient's social circle who may be carrying the same type of HIV. Blood belongs to the individual, Mr. Rose said, and no one should be taking people's bodily fluids for use without full consent. Twenty years ago, CDC recommended that doctors routinely give HIV tests to all patients between 13 and 64 years old. If doctors had done that, this current mess would not exist. The health care system is looking for ways to skirt around things like partner notification; instead it is digging around to find out who might have HIV and who they might be sharing it with. Mr. Rose said he was disappointed by CDC's weak response to PACHA'S recommendations, noting that CDC did not send a representative to respond at this PACHA meeting but rather handed the task to Mr. Philips. Mr. Rose characterized CDC's response as dismissive, and it seems as if PACHA does not have any more to say. ONAP and CDC say they cannot advocate for changing HIV criminalization laws. State health departments say that nothing can be done about criminalization, but they can keep collecting data—and their databases are subject to criminal investigation. That must change. Mr. Rose hoped PACHA would go back to CDC with its recommendations and make the case again.

**Amir Sadeghi with the Community Health Law Project (CHLP)** said that people living with HIV and human rights activists have been sounding the alarm about MHS for years. There is consensus among national HIV advocacy organizations that mandating MHS for every State and jurisdiction without first protecting public health data from being accessed by law enforcement or immigration enforcement represents a dangerous subversion of public health. CDC's guidelines and new assessment tools make it clear that molecular data and other medical information can be protected "except where the release is required by local and State laws." Many State laws expressly permit and even force health departments to share data with police and prosecutors. On the State level, privacy protections usually include carveouts for law enforcement. Public health cannot exist if people are criminalized for their health status and their medical information can be used to prosecute them. People living with HIV are violently and broadly criminalized in most States. Any discussion of MHS that does not start from that premise is fundamentally flawed. Collecting data without protecting it first is just giving law enforcement an incentive to use it against HIV communities. HHS and OIDP recently proposed creating a Federal database, including medical records, to track up to 200,000 low-income PrEP users. A new Oklahoma law establishes a database to surveil patients' medical health information. In Texas, the attorney general sought access to State driver's license data in an effort to hunt down



transgender residents. Surveillance and dehumanizing approaches that potentially hand over information to police and prosecutors are on the rise, threatening health outcomes. CDC, ONAP, and PACHA must work together to ensure that any further implementation of MHS is conditioned on firewalls, prohibiting any and all public health data from being accessed or used by police, prosecutors, and immigration enforcement. In closing, Mr. Sadeghi urged that any future meetings between PACHA and CDC about implementing the MHS resolution be accessible to the public.

**Benjamin Brooks of Whitman Walker Health**, an FQHC, said his organization is a partner in advancing the health of minority communities. He also serves as co-chair of the AIDS United Medical HIV Surveillance Committee which, along with many other groups, has raised issues around privacy, confidentiality, and consent with MHS. Mr. Brooks pointed out that everyone in the room is aligned around addressing the root causes of structural racism. Research conducted by Whitman Walker Health, Georgetown University's O'Neill Institute, and others determined that criminalization is the number-one cause of harm, marginalization, and stigma, particularly among people who are engaged in sex work, transgender women of color, and Black gay men. Mr. Brooks hoped for consensus around decriminalizing sex work, poverty, and other things that he cannot name because his organization receives Federal funding, which severely implicates the ability and moral capacity to advocate on behalf of patients. This weakness is structural and deeply implicated in this country's racist history. Mr. Brooks said FQHCs such as Whitman Walker Health, HHS, the U.S. Census, and others are working toward SOGI data inclusion and expanding access to LGBTQI+ culturally competent education for health care providers, so that patients feel safe disclosing who they really are and what they need. FQHCs in the States fighting back against attacks on gender-affirming care for transgender youth. FQHCs across the country are working on these initiatives, but they are underresourced and lack the money or staff to support the effort. Still, employees take on the work because it is at the heart of their mission. Mr. Brooks asked for more support, more communication, and more connection among partners around these issues.

**Leanne Antonio Sanchez**, leader for an organization that provides services for Latin communities in some States of the Deep South (whose comments were translated by PACE officer LTC Rodrigo Chavez), said their organization represents a diverse spectrum of intersections. They questioned the lack of diverse representation on the Council, particularly representation from Latin and indigenous communities, adding that Native Americans are the only ones considered as aboriginal. Latin American indigenous populations are not taken into consideration. Mx. Sanchez said that statistics still deny the identify of transgender women, counting them as males having sex with males, which has an impact on clinics and hospitals where services are provided. There is no way of changing the sex or gender marker when services are received, so transgender people are victims of double or triple discrimination. Mx. Sanchez described their experience being incarcerated in an immigration detention center, saying they were not provided treatment for HIV, and all those detained individuals living with HIV were put in dark cells as punishment for their condition, in unhealthy and inhumane conditions. Mx. Sanchez asked how such individuals could get comprehensive health services. Undocumented individuals must seek refuge and help in private clinics, which are very expensive. As a consequence, immigrants come to the United States to work but do not have access to services that should be accessible without regard to immigration status. Georgia just passed a law, [SB140](#), and Mx. Sanchez asked how is it possible that the governor is using

immigrants as political bait and even affecting children's livelihood, considering that the State has already invested funding to protect children.

**Martha Cameron, executive director of International Community of Women Living with HIV and vice chair of the People Living with HIV Caucus**, stated that she would like to revoke any consent she unknowingly provided for MHS or CDR until the data of people with HIV can be protected. Her organizations applauded the revised breast- and chestfeeding guidelines, which give good information about the benefits of breastfeeding; describe the effects of structural racism, poverty, and segregation; and offer inclusive language and guidance for transgender and gender-diverse populations. However, these guidelines are not being translated into the community. Providers who treat women living with HIV are unaware of the updated guidelines and the additional services, care, navigation, and education that women living with HIV need. The new guidelines specify that it is not appropriate to call child protective services when a woman with HIV chooses or even asks to breastfeed her infant (because of fears that breastfeeding endangers the life of the child), but it is not clear that providers or child protective services workers know this. Ms. Cameron described her own experience with provider stigma when she was pregnant, noting that it is just one example of the stigma and discrimination that women, and especially women of color, face when they try to access reproductive services. Stigma is heightened for transgender and gender-nonconforming folks. Ms. Cameron stressed that updating guidelines is not enough; there must be education to ensure the safety of people affected by them. Ms. Cameron appreciated the NHAS quality-of-life indicators, but there is no framework for monitoring them. She suggested collecting baseline indicators about Department of Labor efforts around employment or SAMHSA efforts to address mental health. HRSA is responding, but the community has not been broadly engaged to monitor how these indicators are implemented. Ms. Cameron called on PACHA to engage the community in ensuring the quality of life for people already living and aging with HIV.

**Hermeyone Bell, a nurse practitioner in Atlanta, GA**, has cared for people living with and vulnerable to acquiring HIV since the epidemic was identified. She recognized early on that HIV could affect anyone who was sexually active, regardless of ethnicity, gender, identity, or sexual orientation. She questioned the information available in the early 1980s that said HIV affected only white gay men and people who injected drugs, because it did not make sense. As an African American woman who is also left-handed and bisexual, Ms. Bell said she demonstrates the intersectionality of humanity that is often overlooked or unseen by those who "know better" but continue to not do better. In the past 40 years, progress has been made, but there is still a long road ahead unless the epidemic is addressed among Black women, Black heterosexual men, and transgender men. Most research funding and current strategies still focus on men who have sex with men. An active member of the Metropolitan Atlanta HIV Services Planning Council, Ms. Bell applauded that group's work serving the county but called for a closer look at how funding is allocated in the community. Funding should go to services, not agencies. Ms. Bell described patients who are eligible for dental and housing services but cannot get them because of complicated, conflicting regulations. She called for raising awareness among health care providers outside of Ryan White and EHE programs, including primary care providers, gynecologists, obstetricians, and urologists. It is infuriating that some providers specialize in "private" body parts but do not know or want to know about PrEP or postexposure prophylaxis. Health care providers have a responsibility to educate patients and other providers about HIV care, treatment, and prevention. Just as patients with HIV are aging, so are their providers.

**Sierra “Cece” Coven of the Well Project** said that HHS’ updated perinatal HIV clinical guidelines and the changes regarding infant feeding are a step in the right direction and could not have happened without the united voices of the community. The statement that child protective services should not be engaged in response to infant feeding choices is extremely important. Parents living with HIV who consider breast- or chestfeeding in the United States have too frequently been considered a threat to their children. By removing this threat, pregnant people living with HIV will have more confidence to exert agency over their bodies and how they care for their families. Ms. Coven felt privileged to have the resources and support to breastfeed her second child, but privilege should not dictate access. Breast- or chestfeeding is the healthiest option for infant feeding for the general population and the standard of care for those living with HIV in resource-limited settings globally. The limited research on breastfeeding and HIV in high-resource settings has resulted in a lack of education and clinical standards to inform infant feeding decisions. Ms. Coven appreciated the updated guidelines but said the work is not done. Diverse intersecting communities must be armed with the new information and tools to engage in shared decision making, supported by concrete research on breast- and chestfeeding in the United States. The Well Project proposes that PACHA advocate for (1) dedicated research funding to understand the dynamics and experiences around breast- and chestfeeding among U.S. parents living with HIV; (2) a commitment to disseminate, address, and implement the updated guidelines across all Federal agencies and in NHAS and EHE plans; and (3) development of tools that encourage providers to engage in practices centering people living with HIV rather than a dynamic that too frequently threatens the bodily autonomy of those receiving care.

**Mark Misrok, executive director for the National Working Positive Coalition**, said he revoked his consent for the sharing of any health information related to his HIV diagnosis, genotyping, or other related information. He summarized CDC data indicating that as of 2020, greater than 40 percent of people living with HIV were unemployed and 35 percent reported living in poverty. In mid-March, hundreds of people living with HIV and advocacy allies convened for the AIDSWatch meetings and visits to their Congressional representatives. Throughout the meeting, numerous people sought out Mr. Misrok for information on employment, because they were struggling with a lack of assistance from HIV service providers. He said he would continue to speak to PACHA as long as there are no effective efforts from the HIV/AIDS Bureau to connect Ryan White program participants with the information, services, and resources needed to navigate their goals for employment and escape enforced poverty. CDC acknowledges the powerful influence of social determinants of health, including employment, on vulnerability to acquiring HIV and other health risks but does not take action to intervene. The departments of Labor and Education do not partner with HRSA or CDC on HIV care and prevention, and so they do not bring their resources and expertise to address employment needs in communities that have been severely underserved. Mr. Misrok asked PACHA to gather more information about employment needs and strategies and their importance in the domestic HIV response. PACHA should develop a resolution calling for substantive action, going beyond research and meetings, to create access to the employment-related information, services, and resources that would allow more people living with HIV to escape poverty through employment of their choice and reduce new HIV acquisition related to poverty, unemployment, and underemployment.

**Nana Khanna of the Positive Women’s Network and the U.S. People Living with HIV Caucus** said she revoked her consent for the sharing of any health information related to her HIV diagnosis, genotyping, or any other related information. The President’s proposed budget recommends flat funding for the Ryan White program, which sends a clear signal about the administration’s priorities. With the number of people aging with HIV who have comorbidities and greater need, flat funding is actually a cut, even without considering inflation. The quality-of-life goals for people living with HIV cannot be accomplished without investment that reflects the values expressed by those goals. The EHE initiative is predicated on violating the human rights of people living with HIV and promotes status-neutral approaches, despite the lack of documentation about how the shift impacts services. The failure of the EHE initiative is outrageous. The U.S. HIV epidemic is minimally about biomedical treatment and health care advances and mostly about politics, culture, stigma, discrimination, racism—especially anti-Blackness—queer phobia, transphobia, and whose lives are valued. Ms. Khanna urged PACHA to continue to look into MHS/CDR. The assertion that MHS addresses racial inequities does not correspond with what the Positive Women’s Network has heard from public health departments about resources being reallocated away from essential programs and services that reach the hardest-to-reach communities, especially Black and Indigenous people of color (BIPOC), queer people, and transgender folks. With respect to community engagement, Ms. Khanna called for structured involvement, not tokenistic engagement at the CDC’s discretion. With respect to data protections, Ms. Khanna said it is unacceptable to say that CDC has no role. CDC, the Federal government, and PACHA must use every lever available to ensure consistent and robust data protections, regardless of who people are and where they live. Ms. Khanna pointed out that stigma comes from internalizing systemic discrimination and structural violence. She urged the Council and its Federal partners to put protections in place now and to shut down data collection and surveillance that place BIPOC, queer, and transgender communities in harm’s way.

**Terri Wilder of SAGE** called on CDC to remove the upper recommended age limit for HIV testing (64 years). Despite the fact that many older adults and their providers do not think that older people are vulnerable to HIV, data from 2020 show that approximately 17 percent of new HIV diagnoses in the United States occurred among people aged 50 and older. Failure to engage adults of all ages in HIV testing undercuts test-and-treat strategies for prevention and EHE goals. Some experts argue that HIV testing should be a routine part of health care for all adults regardless of age. In November 2016, New York State removed the upper age limit for recommended HIV testing. The offer of HIV testing is most effective when presented as a clinical recommendation by the health care provider. Changing the CDC guidance will require pressure from advocates on CDC leadership and public comments to the USPSTF. HRSA should strongly encourage Ryan White programs to target HIV testing resources to older adults by ensuring that planning councils include such testing as a priority and that contracts are secured with organizations most able to reach these individuals. CDC and its partner agencies should increase collaboration across HIV service testing networks, the aging network, and faith-based community organizations to improve HIV testing rates among older adults. Additional measures must also be taken to advance HIV prevention services among older adults. Ms. Wilder asked that PACHA consider a resolution lifting the age limit for HIV testing and calling for more resources to be allocated around HIV prevention for older adults.

## **PACHA to the People: Community Engagement Session**

The PACHA co-chairs invited all those participating (in person and virtually) to speak. Key comments are summarized here according to the main themes. Dr. Wiesman noted that PACHA will discuss the ONAP/CDC response to its resolution on MHS/CDR on the second day of this meeting.

### **MHS/CDR**

- CDC's focus on gathering comprehensive data could have the unintended effect of driving people away from HIV care.
- Research and evaluation are needed to demonstrate that MHS/CDR is more effective than traditional approaches to detecting disease.
- CDC seems determined to find a way to collect names of people with HIV. It is difficult to believe that collecting DNA from people with HIV will help end HIV.

### **Vulnerable Populations**

- CMS does not appear to be planning for the number of aging people with HIV who will be eligible for Medicare in the coming years.
- Aging people with HIV experience symptoms of aging prematurely, and their needs cannot wait until they are 65 and eligible for Medicare. Ryan White programs and CBOs need good models of HIV geriatric care.
- State legislatures' attempts to ban care that supports transgender youth could evolve into bans on transgender adults. Novel approaches to gender-affirming care should be considered, such as mobile health units.

### **Research and Policy**

- There is a substantial body of research on issues that affect people with HIV that is not translated into policies and services. For example, the Anal Cancer High-Grade Squamous Intraepithelial Lesions Outcomes Research (ANCHOR) study demonstrated that treating precancerous lesions reduces anal cancer among people with HIV. Will HRSA promote anal cancer screening as it does cervical cancer screening?
- More research is needed on people born with HIV. Many are experiencing premature symptoms associated with aging.
- Advocates continue to fight for more HIV research funding and have yet to see substantial funding, particularly for aging people with HIV.

### **PrEP**

- Ready, Set, PrEP should be modified, because it has not reached communities that benefit. Health care providers, such as internists and obstetrician–gynecologists, are not aware of the program. Some health care providers believe that PrEP must be prescribed by a facility or clinician that specializes in HIV.
- Some private-sector health care providers prescribe PrEP without recommending laboratory follow-up testing or ongoing care or discussing STIs.
- Stigma persists around the use of PrEP. All the commercial advertising about PrEP depicts HIV as a disease that only affects gay men.

- PACHA should strive to ensure that there is an opportunity for public comment on the proposed new national PrEP program.

### **Education of Health Care Providers**

- PACHA should work with Federal partners to address the needs of health care professionals for education and guidance on sexual health and gender and sexual diversity. Many medical providers are uncomfortable talking to patients about sexual health or treating transgender or gender-nonconforming patients, which leads to late diagnoses and missed opportunities for prevention.
- Health care providers need education about the updated guidelines for breast- and chestfeeding.
- All new health care guidelines should be paired with mandatory continuing education for health care providers.

### **Status-Neutral HIV Prevention**

- The status-neutral approach could help people affected by disparities, but it can also result in taking much-needed funding away from people with HIV. Braiding funding might be helpful in some cases but not for organizations that only receive Ryan White funding.
- Federal agencies and the clinical providers they fund must be held accountable by monitoring, evaluating, and reporting on the units of service provided using the status-neutral approach and the impact of those services.
- PACHA agrees that additional funds are needed to support a status-neutral approach to HIV prevention.

### **Public Input**

- PACHA should integrate language justice by ensuring that non-English speakers have adequate time to give public comment with translation and that the videoconferencing platform includes interpretation.

### **Funding**

- Funding should seek to promote access to needed care and services; it is absurd that some organizations cannot use their funding for both HIV and STI testing.

### **Closing Remarks and Recess**

Ms. Hayes thanked the team at OIDP that supports PACHA. Dr. Wiesman thanked the participants for their comments. Ms. McNeese appreciated the rich discussion, especially the call for PACHA to facilitate a deeper discussion about structural racism. She recessed the meeting for the day at 5:55 p.m. ET.

## Day 2

### Opening Remarks from the PACHA Co-Chairs

*Marlene McNeese and John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chairs*

Ms. McNeese welcomed the participants at 9 a.m. ET. She reviewed the proceedings of Day 1 and the agenda for Day 2.

### Roll Call

*B. Kaye Hayes, M.P.A., PACHA Executive Director; Director, OIDP; Deputy Assistant Secretary for Infectious Disease, OASH, HHS*

Ms. Hayes called the roll.

### PACHA Subcommittee Reports

#### EHE and the Updated NHAS

*Carl Schmid, M.B.A., Co-Chair*

Mr. Schmid reported that the Subcommittee has been meeting with various Federal partners in an effort to establish ongoing partnerships—for example, with CMS, which has a critical role in HIV prevention and treatment. He said it would look at data, such as data from AHEAD on key components of EHE, as well as data from individual agencies' programs. The Subcommittee is concerned about the limited funding received for HIV programs. While the President's proposed FY 2024 budget includes funding for a new national PrEP program, in 2023, Congress authorized no funding for PrEP except for community health centers. The Subcommittee is following up with BPHC on how that funding was used. Mr. Schmid said the Subcommittee will focus on CDC, which has more leeway than other agencies to support PrEP

The Subcommittee will also look into a tentative proposal by OIDP to collect data through Ready, Set, PrEP. Ms. McNeese asked the Subcommittee to assess the potential to draw new partners into EHE, such as the departments of Labor and Education. Mr. Schmid agreed and noted that the Department of Justice released a report on HIV in prisons. He also hoped to focus on youth and education. Finally, the Subcommittee recognized that discussion about ending HIV can be confused with the EHE initiative, so PACHA should address the language.

#### The Global Agenda

*Jen Kates, Ph.D., Co-Chair*

Dr. Kates said that the Subcommittee works to ensure that global issues are integrated into the agenda at every PACHA meeting and to identify areas for bidirectional learning, such as the panel on Day 1 of this meeting. A PEPFAR representative now regularly attends PACHA meetings as a Federal partner. For future discussion, the Subcommittee would like to work with other PACHA subcommittees on addressing the challenges that women and girls face around HIV, better engaging CBOs and civil society organizations, and promoting rapid start interventions. Dr. Kates said the Subcommittee is interested in any topic that can be informed by PEPFAR's work.

## **Stigma and Disparities**

*Justin C. Smith, M.S., M.P.H., and Rafaelé Narváez, Co-Chairs*

Mr. Smith said that the Subcommittee held an in-person strategic planning meeting to map out goals for the year. MHS/CDR is an ongoing topic for the Subcommittee. The Subcommittee heard presentations from Dr. Harrison of OIDP on MHAF and will soon meet with a HUD representative about HOPWA. The Subcommittee is drafting the PACHA Principles, which defines a vision of a stigma-free environment for addressing HIV, which it hopes to finalize in time for Zero HIV Stigma day in July. Workforce issues have arisen repeatedly in PACHA discussion for years, and the Subcommittee aims to highlight the important role of nonclinical staff in effective prevention and treatment. Another priority is ensuring that a new national PrEP program fully incorporates the principles of equity. Mr. Smith said that PACHA's site visits demonstrate the value that community-led organizations bring to the work. Dr. Wiesman added that public health professionals should be aware of what CBOs have to offer, especially in an PHE. Leo Moore, M.D., M.S.H.P.M., appreciated seeing innovative models for ensuring that the workforce represents the community served and encouraged others to bring such models to the Subcommittee's attention.

## **White House Update: ONAP Update and NHAS Priorities**

*Harold J. Phillips, M.R.P., Director, ONAP*

Although the President's proposed budget for FY 2024 reflects the administration's priorities and calls for increased funding for EHE activities, Congress did not fund Federal HIV programs in FY 2023 at the levels requested. Despite great progress, without full investment, it will be very difficult to meet HIV reduction goals for 2025 and 2030. Mr. Phillips said that decision makers should receive more education on the successes of EHE, such as jurisdictions meeting linkage targets ahead of schedule, and should be encouraged to invest heavily in EHE.

Several Federal actions boost NHAS implementation. HHS updated its guidelines on infant feeding, FDA released draft guidance on updated risk assessment protocols for blood donation, and CMS is developing a national coverage decision on Medicare coverage of PrEP. The Department of Defense added information and tools for PrEP to its website. The Department of Justice released recent data on HIV in prisons. Corporate partners launched the U.S. Business Action to End HIV, a coalition that supports the NHAS goals. The group seeks to promote best practices; encourage internal review of policies, including employer-sponsored insurance; and facilitate industry action, beginning with retail pharmacies.

The NHAS increased the focus on the syndemic of STIs. Mr. Phillips acknowledged the need to better communicate the status-neutral approach, which aims to ensure everyone can access services. The NHAS catalyzed a Federal collaboration to address methamphetamine use. Mr. Phillips said efforts are ongoing to update HIV criminalization laws, disseminate and implement best practices and evidence-based interventions, and engage more Federal partners whose programs affect the quality of life of people with HIV. Mr. Phillips also noted that beginning April 1, some people who were eligible for Medicaid as a result of the PHE will be disenrolled, which means some people with HIV could lose their coverage and access to medications.



## Discussion

Laura Platero, J.D., called on PACHA members and others to support HIV funding for Tribal communities. During the PHE, agencies were able to transfer funds to help IHS reach its HIV prevention and treatment goals. There is some funding for an AI/AN AETC, but more is needed to combat the syndemic.

## Update on Mpox

*Demetre Daskalakis, M.D., M.P.H., White House National Monkeypox Response Deputy Coordinator, Director, Division of HIV Prevention, NCHHSTP, CDC*

Dr. Daskalakis explained that syndemics are epidemics that interact with each other and through that interaction increase adverse effects on the health of communities that face systematic, structural, and other inequities. People who had both HIV and mpox had worse symptoms and more hospitalizations than people who had mpox only, and the worse the HIV (e.g., low T-cell count), the worse the mpox experience. Of people with HIV and mpox, few were on HIV medication. A CDC assessment of 57 cases found that 68 percent of people with severe mpox were Black, and 23 percent were experiencing homelessness, suggesting that social factors contribute to disease severity and compounds the interaction in a syndemic.

Dr. Daskalakis said that HIV prevention and treatment help address mpox, and mpox prevention and treatment are a gateway to HIV and STI services. With the mpox outbreak, federally funded organizations were granted flexible funding to apply a comprehensive, status-neutral approach that included health care, behavioral health care, housing, and other services for people with mpox. The HIV epidemic infrastructure was leveraged to control mpox. Dr. Daskalakis envisioned a national PrEP program—linked with the Ryan White program, CDC assets, and SAMHSA resources—that could be adapted for outbreaks like mpox.

As of late March, more than 30,000 cases of mpox had been reported in the United States, with 38 deaths, said Dr. Daskalakis. The virus persists, but transmission is declining, albeit slowly. More work is needed to vaccinate, test, and treat people to stem the current outbreak and prevent future outbreaks. Most cases occur in cisgender men and are transmitted by male-to-male sexual contact. About 60 percent of cases occur in Black and Latino people. To date, 1.2 million vaccine doses have been administered. Vaccination rates by race and ethnicity do not align with the distribution of cases by race and ethnicity. CDC guidance on how to expand vaccinations reflects public input on how to respond to concerns and answer patients' questions. With summer coming, HIV resources should be leveraged to prevent a new mpox spike.

The U.S. government is hosting an mpox research gathering and recently released an updated inventory of mpox research to date. Dr. Daskalakis said that the research response around mpox has been historic, because the government was able to identify priorities in the midst of the outbreak and account for all of its work, which could be a model for future disease outbreaks. CDC has launched a [website](#) with information on how LGBTQI+ people can stay healthy during Pride month and in general. It includes resources on mpox, HIV, STIs, and overdose prevention, among other topics. Upcoming data on vaccination by jurisdiction will show that the likelihood of a large mpox outbreak is greater in jurisdictions where less than 30 percent of people are vaccinated. The data bolster the case for increasing mpox vaccination rates.

## **FDA Blood Donor Policy Update**

*Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, FDA*

In January 2023, FDA released draft guidance on eligibility for blood donation by people with HIV. Canada and the United Kingdom both offer individual risk assessment to evaluate eligibility. The Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) study collected data in several cities where HIV transmission rates are significant. The COVID-19 pandemic hit in the middle of participant enrollment, but the study managed to get close to its target enrollment and fund more follow-up interviews than expected. Quantitative data from the study informed the FDA draft guidance, and the full results will be publicly presented soon.

The draft guidance proposes permanent deferral of anyone who has ever had a confirmed positive HIV test result or has taken medication to treat HIV. People taking PrEP would be deferred for 3 months if they take medication orally and 2 years if they use injectable medication. Dr. Marks acknowledged that the duration of deferral for people on PrEP reduces the potential donor pool. FDA intends to determine whether some people taking PrEP might be eligible to donate, but the current proposal enables FDA to move forward without waiting for additional data. Finally, potential donors, regardless of gender, would be deferred for 3 months if, over the past 3 months, they have had a new sexual partner, anal sex, or more than one sexual partner and anal sex. Having a single set of questions for all potential donors helps, said Dr. Marks. He added that the few countries whose donation policies do not automatically defer people using PrEP (e.g., Italy, Israel) do so in practice through oral questions asked by a physician. FDA hoped to finalize the draft guidance by June.

## **Federal Update on Substance Misuse and Drug Overdoses**

### **CDC Data on Overdoses**

*Grant Baldwin, Ph.D., M.P.H., Director, Division of Overdose Prevention, National Center for Injury Prevention and Control, CDC*

Dr. Baldwin said the 107,000 overdose deaths recorded in 2021 were driven by the increasing burden of illicit fentanyl, challenges posed by COVID-19, and the increasing involvement of multiple substances in overdose deaths. Notably, deaths from overdoses that do not involve fentanyl decreased. The pandemic increased all overdose trends, particularly overdoses involving synthetic fentanyl. Opioid-related overdose deaths have been rising since 2000 and have accelerated since the introduction of synthetic fentanyl in 2013. In earlier research, the opioid crisis was most apparent among White men in rural areas, but now it affects every demographic, with huge increases among Black and AI/AN people.

Historically, a user's risk for nonfatal overdose increased with growing frequency of use. The presence of fentanyl increases the risk dramatically at initiation and at every point along the continuum of drug use from initiation to SUD. Synthetic fentanyl is easy and inexpensive to produce, easy to transport, and highly profitable. Substance use is higher among people with any mental illness and higher still among those with severe mental illness, which highlights potential comorbidity that merits more attention and resources. Having adverse childhood experiences (ACEs) increases the risk of substance use.

To address overdoses, CDC recommends strengthening prevention efforts with a focus on ACEs; supporting harm reduction, expanding naloxone use, and providing overdose prevention education; expanding access to SUD treatment and wraparound services; initiating early interventions with people at high risk for overdose; and improving detection of overdose outbreaks caused by fentanyl and related drugs to facilitate response. The HHS Overdose Prevention Strategy aligns key CDC investments around harm reduction, primary prevention, recovery support, and evidence-based treatment. CDC's guiding principles for preventing overdoses and substance use harm focus on promoting equity and addressing underlying factors, as well as advancing partnerships, evidence-based action, science, and innovation. CDC also articulates strategic priorities around monitoring trends, building capacity, supporting providers, fostering partnerships, and raising public awareness (e.g., CDC's [Stop Overdose](#) and [Rx Awareness](#) campaigns).

### **Addressing HIV and the Overdose Crisis**

*Redonna K. Chandler, Ph.D., Director, HIV Research Program and HEALing Communities Study, NIH Helping to End Addiction Long-term (HEAL) Initiative*

Dr. Chandler commented that everyone at high risk for an overdose fatality is also at risk for HIV (or has HIV), and HIV programs have an opportunity to prevent overdose. As with HIV, overdoses and SUD are exacerbated by unstable housing, HIV, and hepatitis C infection, among other social determinants of health.

Intranasal naloxone can prevent overdose deaths and is easy to administer, but most States still do not have sufficient access to naloxone, especially among rural populations and among certain racial and ethnic populations. There are effective medications to treat OUDs that significantly decrease the risk of death and lower the risk of HIV and hepatitis C transmission. Moreover, among people with HIV, medications for OUD improve retention in treatment and outcomes. Despite these positive outcomes, medications for OUD are underused in the United States and internationally.

Provider stigma against drug users, especially against people who inject drugs, has a significant impact on people with HIV. A significant number of providers have explicit or implicit bias against people who inject drugs and would defer antiretroviral therapy or PrEP for those patients. Many people with HIV use opioids for chronic pain, putting them at high risk for overdose. Dr. Chandler emphasized that harm reduction for overdose risk can be integrated into HIV care. As with HIV, efforts to reduce overdose risk must strive to meet people where they are and to initiate treatment rapidly, with attention to geographic and transportation disparities, among other social determinants of health. Dr. Chandler listed a number of specific harm reduction services that could be incorporated into HIV care, which would reduce overdose fatalities, reduce the risk of HIV and other infectious diseases, and link and retain more people in care. She encouraged PACHA to call out stigma against people who inject drugs; demand high-quality health care that addresses SUDs and HIV; and appoint people with experience with substance use, including current users, to PACHA, and encourage their participation in community advocacy. PACHA can also promote integrated care that fully addresses patients' needs and highlight the need for ongoing research to help organizations deliver tailored responses to overdose risk, SUDs, HIV, and other needs.

## Discussion

Dr. Baldwin said CDC is making a significant investment to address overdoses in Tribal communities. The agency recently hired a health equity officer to ensure that it follows an equitable approach to all of its drug overdose activities.

Dr. Guillamo-Ramos emphasized the need to make naloxone more accessible. He appreciated that SAMHSA removed some barriers to prescribing medications for OUDs. Dr. Guillamo-Ramos said nurses are the country's largest workforce and have a role to play in overdose intervention and getting people who have overdosed into treatment quickly. Dr. Chandler said that NIH's National Institute on Drug Abuse is conducting research on the best approaches to treatment for OUDs.

## Addressing HIV and Substance Misuse from a Community Perspective

*Co-Facilitators: John Wiesman, Dr.P.H., M.P.H., and Darrell P. Wheeler, Ph.D., M.P.H., M.S.W., PACHA Members*

*Panelists: Cyndee Clay, Executive Director, Honoring Individual Power and Strength (HIPS)*  
*R. Lyle Cooper, Ph.D., M.S.S.W., Associate Professor; Co-Director, Addiction Medicine Residency Training; Director of Didactics, Mid-South Addiction Medicine Fellowship; Founder and Co-Director, Meharry Addiction Clinic; Department of Family and Community Medicine; Meharry Medical College*  
*A. Toni Young, Founder, Executive Director, Community Education Group*

Panelists described their organizations and offered their initial thoughts on potential PACHA priorities. Ms. Clay looked forward to sharing some of her organization's successes around HIV prevention as well as current challenges. Ms. Young said her organization transferred lessons learned from successful programs in Washington, DC, to rural Appalachia, which needs more attention. She recommended that PACHA hold a meeting in West Virginia in partnership with the Appalachian Regional Commission to better appreciate the needs of Appalachian communities.

Dr. Cooper described an array of substance misuse services that Meharry Medical College supports, which together provide an avenue for training new physicians on SUDs, PrEP, HIV testing, harm reduction, and recovery. Providing services in Tennessee is becoming increasingly difficult as the political climate is growing more hostile to the LGBTQI+ community. The State has not expanded its Medicaid program and recently said it would return CDC funding for HIV.

To preface the discussion, Dr. Wheeler outlined three themes. First, medicalizing treatment does not account for the cultural, historical, and emotional roots of bias and discrimination. Second, the concept of "meeting people where they are" ignores the relationship between the provider and the individual served and the provider's impact on the individual's care. Third, there is tremendous lag time between the recognition of effective interventions and their implementation. PACHA and other must recognize that communities have been calling for harm reduction,

housing, and other interventions for 40 years without being heard. Only now are those communities being invited to the table.

Ms. Young explained that some parts of the country, such as rural America, did not have these conversations until the opioid crisis emerged. In some rural areas, there is no political will to provide services for people who use drugs. West Virginia has the highest rates of overdose deaths but only nine methadone programs and a moratorium on opening new ones. Ms. Young added that once providers of medication for SUDs receive their State licenses, they face no requirements to maintain or renew licenses, which represents a missed opportunity for educating about screening for HIV and hepatitis C and linking people to care. Training peer navigators and identifying potential partners are also key steps. Settlements with makers of opioids brought forth billions of dollars, but that money is not going to local public health departments, Ms. Young observed.

Ms. Clay noted that Washington, DC, has been very progressive and innovative in its work around HIV, but strong programs are being dismantled. Opioid settlement money, especially for programs for people who use drugs, is funneled through the Department of Behavioral Health, which has little experience with effective behavioral interventions other than abstinence and little to no community engagement. Money is being diverted away from HIV/AIDS programs. HIV service organizations created the model for a comprehensive approach that was leveraged to respond to COVID-19 and mpox, and harm reduction organizations have been meeting people where they are for 30 years. Now, even highly successful harm reduction programs lack sustainable funding that supports prescription approaches to treatment. All of these programs deserve continued funding and a share of the opioid settlement money.

Dr. Cooper echoed Ms. Young, observing that some parts of the country never acted on the calls for harm reduction services and housing as treatment over the past 40 years. Until recently, applicants for Federal funds were discouraged from mentioning harm reduction initiatives. Despite recent policies allowing funded organizations to purchase harm reduction supplies, the country is far behind where it needs to be. PACHA should consider how States that do not have Medicaid expansion can pay for harm reduction supplies. Dr. Cooper emphasized that clean syringes save lives, and syringe services are one way to build relationships with people who mistrust the medical establishment. In health care settings, lack of cross-disciplinary training among providers means many people are not referred to the care they need.

Ms. Young said CDC's creation of an Office of Rural Health is a step toward recognizing the needs of rural communities. She suggested eliminating the rural health calculators used to determine grant eligibility and finding a better mechanism that enables organizations that serve multiple counties and States to apply for Federal funds. Furthermore, sustainability should not rely on Federal funding, because priorities change with administrations. Corporations must be engaged in finding solutions. Businesses must be willing to invest in communities and grow the workforce they need to operate. Dr. Cooper added that sustainability is especially difficult in areas that lack publicly financed health care options.

Ms. Clay agreed with Dr. Cooper that syringes save lives. Since Washington, DC, allowed organizations such as hers to run needle exchange programs, HIV rates among people who inject drugs have plummeted to near zero. Despite the evidence, funders refuse to recognize that harm

reduction prevents HIV infection and engages people in care. Overdose prevention centers can be venues for vaccinations, overdose education, and linkages to care. Biomedical strategies are an important part of changing behavior, but they do not work if the people who need them do not have access to them or feel safe accessing them.

Dr. Cooper noted that there is still institutionalized resistance to hiring peer workers, and once hired, peer workers often are not paid a living wage. Their ability to connect with people who use the services is valuable beyond measure in building relationships and fostering engagement. Ms. Clay added that current guidelines require peer recovery support specialists to be abstinent, which poses barriers. Ms. Young proposed creating national definitions for the positions of peer recovery coaches, community health workers, and the like, rather than relying on States to create their own. In addition, providers of medical treatment for SUDs must be educated about behavioral models and approaches, such as peer recovery coaching, that can contribute to recovery.

Ms. McNeese noted that PACHA can look more closely at how Federal program guidelines and how flexibility translate into services on the ground. She shared Ms. Young's concerns about the opioid settlement dollars, noting that in Texas, that money is going to law enforcement rather than public health.

Ms. Roha acknowledged concerns that peer workers are often underpaid if they lack educational degrees. SAMHSA is seeking to eliminate education requirements for key personnel in its grant programs and encourages hiring people with relevant lived experience in lieu of education.

Ms. Young stated that effective partnerships can occur when each party gets something it wants. In West Virginia, for example, politicians want jobs for their constituents, especially blue collar jobs to make up for the loss of the coal industry. The Community Education Group is advocating for locating manufacturing and service jobs in Appalachia. It also aims to hire peer workers at livable wages, but national standards would help cement those efforts. Ms. Clay emphasized the need to break down unnecessary barriers, such as requiring peer workers to be in recovery or abstinent from drugs.

Dr. Wheeler said there must be recognition that funding in this country is finite, and when one group benefits, another suffers. How dollars are spent is the tangible expression of one's true values.

Dr. Cooper noted that with Tennessee turning away Federal funds for HIV, surveillance will suffer, and the State will not recognize spikes in infection. He hoped mechanisms could be enacted to ensure continued surveillance. He also called for allowing programs to spend Federal funds on harm reduction products other than syringes, such as safe smoking kits. Finally, Dr. Cooper suggested HRSA and SAMHSA continue to expand training on treatment for SUDs, especially OUDs.

## **PACHA Member Reflections**

A number of members expressed appreciation for the site visits, which offer valuable insights. Mr. Schmid relayed news of continued efforts to invalidate ACA provisions that ensure that

effective preventive health services are covered by health insurance plans. Dr. Stewart said that without access to health care, it will be impossible to end HIV.

Ms. Platero looked forward to the next PACHA meeting, which will be held in Arizona, and the opportunity to discuss how health care works in Indian country and the political status of Tribal groups. She hoped to bring the needs of Tribal nations and AI/AN people to the forefront.

Alicia Diggs, M.P.H., said the data on mpox illustrate the need for more education about the disease and better access to vaccines. The gap between vaccination rates and new cases in the African American community is concerning, as is the number of new cases in cisgender women.

Dr. Guillamo-Ramos acknowledged the need to use every tool possible to fight the HIV epidemic and work toward health equity, but more discussion is needed to determine whether MHS/CDR provides information that cannot be gathered in other ways. More examples are needed of how MHS/CDR mitigates HIV risk. Current data appear to show that some HIV clusters have become larger in the wake of MHS/CDR.

Mr. Smith said that the Stigma and Disparities Subcommittee will likely delve further into the issues around substance misuse. Ms. McNeese encouraged the Subcommittee to address provider stigma that hinders access to treatment for SUDs and the negative impact it has on HIV. Dr. Stewart suggested looking more closely at how to leverage the capacity of community health centers to provide prevention and treatment for HIV and OUDs.

Mr. Smith commented that the power of the community, highlighted by the bidirectional learning panel, remains central to PACHA and others. PACHA is committed to eliminating stigma and combating racism. The Council cannot tackle all the barriers, but individual members can use what they learned from presentations and comments to work for change in their communities. Mr. Smith spoke about the need to address the broader landscape of politics, culture, and people that perpetuate stigma. Dr. Stewart suggested that PACHA advocate for implicit bias training early—before medical school or other professional training—and promote a culture of humility.

Dr. Wheeler observed that the United States has a history of not honoring its commitments, which surfaced during this meeting. For PACHA to advise with integrity and honesty, it must interrogate the violations committed in the past and perpetuated. Policies should not continue to accommodate inequity.

Ms. McNeese spoke about her own experience with substance use and recovery. She said community voices are sometimes dismissed as misinformed, despite their experience of how things work on the ground. Ms. McNeese called on PACHA to address the status-neutral approach to care, with attention to varying interpretations and implementation, financial implications, and unintended consequences.

Dr. Wiesman expressed gratitude for the Federal employees who bring their lived experience to the work and share the vision of ending HIV. He encouraged PACHA to acknowledge and celebrate the progress reported at this meeting, which is often initiated by communities and achieved by people in government trying to meet the needs of people they serve.

Dr. Moore said a national PrEP program must consider how to improve uptake, not just access. Mr. Phillips acknowledged that the program should go beyond bulk purchasing. He said that PACHA's insights have helped ONAP frame its priorities. Ms. Hayes noted that OIDP aims to build momentum around issues raised by PACHA, such as outreach to young people and the needs of Black women with HIV. Dr. Daskalakis added that HIV is the model for addressing infectious disease, and support for the HIV infrastructure translates into preparedness for the next outbreak.

## **Next Steps, and Closing Remarks**

*Marlene McNeese and John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chairs*

Dr. Wiesman appreciated all those who make PACHA meetings possible. Ms. McNeese recognized that there are persistent challenges, but also progress, thanks to the resilience of partners and allies. She thanked everyone involved and adjourned the meeting at 2:24 p.m. ET.



## Appendix: Written Public Comments

### Shekinah Rose

Good morning, afternoon or evening from wherever you may be.

My name is Shekinah Rose. I use pronouns (They/Them/Theirs). I am a White Elder Trans Non-Binary Woman living, surviving, and thriving with HIV/AIDS for 38+ years. I have ombre blonde long hair, wear facial makeup, a black and white dress with black and gold necklace and earrings. I'd like to thank Positively Trans for the opportunity to provide you public comment. Thank you to each Presidential Advisory Council Member for the opportunity to discuss HIV+ Trans needs.

I give thanks to past, present, and future people's of the on the land we are on holding this meeting today.

I will speak today as a person of Trans non-binary experience living with HIV/AIDS. I was diagnosed in 2007 with HIV Encephalopathy, brain disease. I am a HIV Trans Advocate and Community Educator. I have been advocating for people with HIV/AIDS since the beginning of the epidemic while living in the City of Los Angeles. We have come a long way since those early years. With safe and effective HIV Drug Treatment, people with and at risk for HIV can live long productive lives. We are making strides in choices available for people at risk of HIV which also includes future interventions to reduce Sexually Transmitted Infections. It's an exciting time in the history of Sexual Health.

I would like to praise and give my thanks to the Biden-Harris Administration for continuing to make improvements in the lives of Americans by funding HIV research, expanding access to both HIV medications and SARS-COV-2, access to and services for people at risk of HIV with access to PrEP on demand. The Biden-Harris Administrations to address & fund Social Determinants of Health programs which are reaching millions of Americans by reducing health inequities, disparities, houselessness, food insecurities, mental health challenges with increased access to physical and mental health. I thank President Biden for the creation of 315 slots for Mental Health Providers. This is a good start to an endemic condition millions of Americans face each day.

I am a Positively Trans National Advisory Board Member, Positive Women's Next work – USA, USPLHIV HIV Caucus Member, Set Project Member, Pennsylvania Governor's Office LGBTQIA Commission Aging Working Group, a Community Member with the Rustbelt Center For AIDS Research CFAR Scientific Working Group, Rustbelt CFAR Sex and Gender Scientific Working Group & Advisory Board Member, a Community Member with the Pennsylvania HIV Planning Group a recently elected Intersectional and Innovation Sub-Committee Co-Chair Elect & Steering Committee Member, Employment working Group, a Community Member of Arizona StateWide Advisory Group, Western Pennsylvania LGBTQ+ Older Adults Advocacy Team & Legislative Sub-Committee Member.

I will begin firstly by acknowledging and give thanks to so many National Transgender Non Conforming HIV Prevention, Gender Affirming Healthcare and Support, Harm Reduction

Advocates and people with Transgender Non Conforming experience in guiding this conversation.

Youth are engaging in sexual experiences at a young age. Sexual health education is key to empowering youth to begin their lives learning how to become proactive in their decision making around sexual health regardless of sex or gender identity. Knowing about and having knowledge of our bodies will work towards reducing STI and acquired HIV diagnosis. This starts at puberty.

We need to have a Sex Education curriculum that acknowledges and respects Trans, Queer young people sexual experiences, the need to discuss PrEP as prevention.

I advocate and ask the Biden-Harris Administration to fund Mindfulness as a necessary tool commencing in primary education. Living in an ever increasing complex world the need for mental health tools to navigate life is critical to good decision making, managing stress & anxiety, reducing the possibility of experiencing trauma, increase ability to stay focused, deal with complex life choices, increase capacities for well-being, stable health, and Joy.

Being involved with the Rustbelt CFAR Scientific Working Group I appreciate research on differences on HIV, Sex and Gender are being studied. I request the Biden-Harris Administration to address research inequities of BIPOC communities, Trans Women & Men, Cis Gender Women. These demographics represent the present and future of people who are at risk for and living with HIV. I implore the Administration to be a voice to increasing necessary clinical studies in the development of appropriate drug treatments that allow people to thrive with HIV similar to cis gender males. It's time to prioritize funding and research in these areas in Ending the HIV Epidemic.

Trans people living with HIV live with barriers reminiscent of the early AIDS days when it was a time of discrimination in housing, jobs, education opportunities, access to care, sexual repression & violence. Black Trans Women face the highest rates of acquired HIV diagnosis and homicide.

We need funding that is flexible, immediate, and pushes for collaboration across all sectors and identity groups. With current Anti-Trans laws we are creating for child refugees across America in 2023. We have 1000's and millions of LGBTQIA population that feel unsafe and want to leave the country. Our communities with both Sex trafficked and people of trans experience who have sought refugee status face greater challenges living with HIV. Being culturally and linguistically appropriate for Trans HIV increases their ability to assimilate and become productive members of the community.

For our Trans Elders access to receiving quality appropriate care in Ages Care facilities requires a overhaul of the way we provide Age Care to all people. I order to feel safe in aged care requires a workforce with new skillsets. Advanced SOGI Training for the workforce will provide a pathway for delivering equitable, culturally and linguistically appropriate services. Treating everyone the same regardless of sex or gender. Paying a living wage, developing Age Care as a viable career choice that is valued.

As in everything, we recognize our ability to have choice in drug treatments, housing options, [sic].

## **Tamara**

My name is Tamara and I want to thank you for the opportunity to submit in writing my public speaking comment. I am a Woman Leader that represents a group that self-identified as Spanish-monolingual Women and our environment friends, Gays .

What is the value of a Program for which the initiative is to end the HIV epidemic if the information doesn't reach everyone because is in English? The US is made up of many nationalities, among the Spanish speakers , a group that reaches 62 million people. These are individuals that work , produce ,contribute, and vote in the United States.

I hope that it won't be a challenge for the Office of the Secretary of Health to recognize that Latin/Hispanic individuals wants Representation from People that look like Us and speak a fluent Spanish Language. We request at Least one Latin / Hispanic Spanish speaker in a Federal Position where the decisions for the Ending the HIV Epidemic initiative are being taken. We deserve to have Representation from People that are fluent in Spanish and are Latin / Hispanic like us living in Latin / Hispanic Countries. We want to have access to everything that is being offered so We can have equal benefits and all together Hispanic/White/ Blacks can end this disease that has taken so many lives , and continue to do so because We do not have the information in our Spanish language. How can We have equity if We do not understand the biomedical benefits and preventive efforts? We need Spanish Materials and information available for all.

We request Secretary Becerra as a Latino to take matters into his own hands on this important issue, because failing to do so will invalidate President Biden's message of Equity. We only want equal treatment and care, something as Humans beings we deserve. We want People that can represent the cultural and linguistic aspects of being a Latin/ Hispanic. People with Latin/ Hispanic lived experiences, that understand out struggles . We only want to end the Epidemic and live with dignity. We talk not only for Us but for the new generations. We want Spanish materials. We want to see in announcements, information on the press, radio, billboards website ( [hiv.gov](https://hiv.gov))calling numbers and everywhere the information could be accessed to be in Spanish . We want representation. We want a Voice . We want equity. We do not want a different parameter for us because we are Latin / Hispanic , and We deserve humane treatment. This humane treatment can only be comprehended by someone that has truly walked in our shoes . Above all we want Spanish speaking people committed to the cause.

Thanks

Tamara Sent from my iPhone

## **Terri Wilder**

Hello, my name is Terri Wilder (she/her), and I am the HIV/Aging Policy Advocate at SAGE. SAGE is the world's largest and oldest organization dedicated to improving the lives of LGBTQ+ elders, including older adults with HIV.

I would like to express my gratitude to PACHA for including a discussion around older people living with HIV and Long-Term Survivors during a recent meeting. At SAGE, we have been working on this issue for some time, dating back to when we created the first support group in the country for older people with HIV.

I want to discuss a crucial need regarding the CDC's HIV testing guidance. Specifically, the CDC should remove the upper recommended age limit for HIV testing. The current US Centers for Disease Control and Prevention (CDC) guidelines state that screening for HIV should be performed routinely for all patients aged 13--64 years. However, our goal is to have the upper age limit removed so that all people aged 13 years and older are included.

Despite the fact that many older adults (and their providers) do not think that older people are at risk for HIV, approximately 17 percent of new HIV diagnoses in the United States in 2020 occurred among people aged 50 years and older. Failure to engage adults of all ages in HIV testing undercuts test-and-treat strategies of prevention and ending the AIDS epidemic goals. While the CDC has not recommended routine HIV testing for adults over the age of 64, some experts argue that HIV testing should be a routine part of healthcare for all adults, regardless of age. In November 2016, New York State passed Public Health Law 2781-a, which removed the upper age limit for recommended HIV testing. The NYS Public Health Law mandates the offer of HIV testing to all patients age 13 or older.

The 2016 amendments to the NYS Public Health Law removed the previous upper age limit of 64. The offer of HIV testing is most effective when it is presented as a clinical recommendation of the health care provider. The offer of HIV testing must be documented in the patient medical record.

SAGE would like to see a change like NYS made via the CDC guidance. To make this change, pressure from advocates, meetings with CDC leadership, and public comment to the US Preventative Task Force will be required.

The Health Resources and Services Administration's (HRSA's) HIV/AIDS Bureau (HAB) should **STRONGLY** encourage Ryan White recipients to use HIV testing resources to specifically target older adults by ensuring that planning councils include such testing as a priority, and that contracts are secured with the organizations most able to reach these individuals. The CDC and its partner agencies should increase collaboration across HIV services/testing networks, the aging network, and faith-based community organizations, to improve HIV testing rates among older adults.

In addition to removing the HIV testing age limit, we must also take additional measures to advance all HIV prevention services among older adults. The CDC and its sister agencies should dedicate resources to developing and evaluating HIV prevention campaigns and interventions

that target older people age 50 and older. These campaigns should also encourage the use of PrEP and PEP among older women and men as well as harm reduction services.

The CDC, with the support of the HIV community and older adults, should develop and disseminate HIV testing/prevention/PrEP/PEP social messaging and marketing campaigns to older adults who are most vulnerable to HIV.

The Office of National AIDS Policy as well as PACHA can openly support these policies for older adults.

In conclusion, I respectfully ask that PACHA consider a resolution around the age limit being lifted for HIV testing and that more resources be allocated around HIV prevention for older adults. Thank you for your time and consideration.

Thanks,

Terri L. Wilder (She/Her), MSW, HIV/Aging Policy Advocate Minneapolis, MN, T: 929-458-2105, [www.sageusa.org](http://www.sageusa.org)

**Ciarra Covin**

Hello,

Please find my public comment below:

As many of us in the HIV community know, on January 31, 2023, the Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States or better known as the Perinatal HIV Clinical Guidelines issued by the US Department of Health and Human Services (HHS) were updated and included some very big changes to the section on Infant Feeding for Individuals with HIV in the United States. These updates are a step in the right direction for the guidance that is given to women and other birthing people living with HIV in the US. This could not have happened without the united and uplifted voices of those in the community. One extremely important change was the addition of a statement that says Child Protective Services (CPS) or similar agencies should not be engaged in response to the infant-feeding choices made by women and other birthing parents living with HIV. Parents who considered breast/chestfeeding in the US have too frequently been considered a threat to their child just due to the fact that they are living with HIV. From my own personal experience, I know that this threat is one of the scariest, and by removing it, pregnant people living with HIV will have more confidence to exert agency over their bodies and how they care for their families.

As a mother living with HIV, who has given birth to two children and had the resources and support to breastfeed my second child, I often feel that I am in a place of privilege because of my proximity and access to these extremely vital means. While I'm grateful for my experience, privilege shouldn't dictate access. Breast/chestfeeding, while a complex issue, is considered both the healthiest option for infant feeding for the general population and the standard of care for women and other birthing parents living with HIV in resource-limited settings globally. It is the limited research on breastfeeding and HIV in high-resource settings that has resulted in a lack of education and clinical standards for providers in these areas to support women living with HIV in making informed infant-feeding decisions. We're gratified but the updates to the Perinatal HIV Clinical Guidelines, but the work is not done.

It is important that we continue to arm our diverse, intersecting communities with the new information contained in these guidelines and provide them with the tools to engage in shared decision-making. This will be much easier to achieve when there is concrete research that is dedicated to breast/chestfeeding among women and other birthing people in the United States, a high-resource country whose guidelines are often referenced throughout the world.

On behalf of myself as a woman living with HIV (who successfully breastfed my one year-old daughter) and The Well Project, I am here to propose that PACHA advocate for the following:

Dedicated research funding to understand the dynamics and experiences around breast/chestfeeding by parents living with HIV in the US

A commitment that guideline changes be disseminated, addressed, and implemented across all federal agencies, the National HIV/AIDS Strategy, and the EHE plans to better serve women and other birthing people living with HIV

The development of tools that encourage providers to engage in practices centering people living with HIV versus a dynamic that too frequently threatens the bodily autonomy of those receiving care because of their HIV status

Thank you,

Ciarra Covin, MS

Program Manager

Pronouns: she/her

Tel: 856-514-1350

The Well Project



## **Hermeyone Bell**

Good afternoon PACHA and community members across the country-

My name is Hermeyone Bell and I am a Nurse Practitioner in Atlanta, GA. I have been providing care to people living with and vulnerable to acquiring HIV since the epidemic was identified. I recognized early on that HIV was not just an illness that affected white, gay men, but affected anyone who was sexually active, regardless of ethnicity, gender identity or sexual orientation. I didn't have the language or words to describe the care I was providing in the early days of the epidemic, I only knew that care was needed. I knew that I was vulnerable to acquiring HIV because of my sexual behaviors, even though the information available in the early 1980s "said" HIV affected white gay men or people who injected drugs. I questioned that narrative early on because it didn't make sense to me. I didn't understand how it only affected certain groups of people if we all, as human beings, have blood in our bodies. Therefore, I consumed as much information as I could to help myself, family, friends, and patients understand their vulnerability to acquiring HIV.

As an African American woman, my appearance is classified as being a minority in this world, being Black and being a woman. I actually identify with two other minority groups that are not seen when you first meet me. I am left-handed in a right-handed world, and I am proud to represent the "B" in the LBGTQI+ community. My very being shows the intersectionality of humanity that is often overlooked or "unseen" by those who know better but continue to not do better.

We have come a long way in the 40+ years of the HIV epidemic, but we still have a long road ahead if we do not address the epidemic in Black Women, Black Heterosexual Men, and Transmen. Yes, Black women are on your radar, but a lot of the programs, research, funding, and current strategies still focus primarily on men who have sex with men.

I have practiced in private and public health settings in Atlanta, GA for the past 35 years. I will be relocating to the Houston, Tx area later this year and will continue to provide care to those living with and vulnerable to acquiring HIV. I am an active member of the Metropolitan Atlanta HIV Services Planning Council and applaud our council on the work that has been done serving the 20 county EMA. However, we need to look at how funding is allocated in our community. We need to fund services and not agencies. For example, I have a patient who needs dental care but is denied this service because he does not receive his primary care at a RW funded agency that has a dental clinic. This RW funded dental clinic still does not meet the standard set by HRSA for oral health even when this service is available to the patients in their program. Additionally, I have a patient who needs housing assistance, but she cannot receive assistance from an agency that receives HOPWA funding because she does not receive her primary care there. They are both eligible for services, based on the eligibility guidelines for RW, EHE, and HOWPA, yet they are unable to access these services because they want to keep me as their healthcare provider. They are told that they must change their healthcare provider to receive the service. This is a barrier. Fund services and not agencies!!

We need education for healthcare providers outside of the RW, EHE, funded providers. Educating Primary Care providers, Gyn/OB, urologists and others who take care of people. It infuriates me that some providers that specialize in our private body parts don't know or don't

want to know about PrEP or PEP. Part of our responsibility as healthcare providers is to educate our patients about their health conditions but it is also our responsibility to educate other providers about HIV care, treatment and prevention. Not only are our patients aging with HIV, but the providers are aging too. I am 61 years old, and I am planning to retire in about 9 years. Throughout my career, I have served as a preceptor, mentor, educator for nurses, doctors, pharmacists, other allied health professionals because I know I will not be able to do this forever. We need to have HIV curriculum incorporated into the basic medical, nursing, and other healthcare degree programs like we have diabetes, hypertension, or other conditions routinely taught. It should not be an elective but mandatory education for healthcare providers.

Lastly, if we are to End the HIV epidemic by 2030, we need to talk about sex. With few exceptions, none of us would be here if not for a sexual encounter. Sex is a natural part of the human experience, yet we rarely talk about it, even with our intimate partners. We all know what it is, but we have been “indoctrinated” to be silent about it. We need to destigmatize the conversations about sex. Talking about sex is the safest way to reduce acquiring HIV and STIs. Talking about sex needs to be normalized, a routine topic to be addressed regarding a person’s health.

Thank you for allowing me to share my experience and comments.

Hermeyone Bell, APRN, BC-FNP, AAHIVS  
Bell Primary Care

## Center for HIV Law & Policy



April 5, 2023

### **It's not Just a State Issue: PACHA, ONAP, and CDC Must Promote the Shielding of Public Health Data from Criminal, Civil, and Immigration Proceedings**

Dear Members of the Presidential Advisory Council on HIV/AIDS,

We are writing to you as The Center for HIV Law & Policy (CHLP), an abolitionist legal and policy organization fighting to end the stigma, discrimination, and violence towards our communities experiencing racial oppression, patriarchal violence, and/or economic divestment. Our work is centered in communities living with and deeply affected by HIV and other stigmatized health conditions. We utilize legal advocacy, high-impact policy and research initiatives, and the creation of multi-issue partnerships, networks, and resources as concrete ways to support our communities working to decriminalize HIV and other stigmatized health conditions.

For years, CHLP has been a proud and leading member of a growing group of people living with HIV (PLHIV), national organizations, privacy experts, and human rights advocates with substantive and serious concerns about the implementation of molecular HIV surveillance (MHS). We are a member of the AIDS United Public Policy Council (PPC), and supported the Council in its Position Statement on MHS<sup>1</sup> as well as its CDC NOFO recommendations.<sup>2</sup> We encourage you to revisit these resources as PACHA deliberates on how to proceed and advise HHS about the persistent risks MHS poses to public trust in the federal response to end the HIV epidemic.

CHLP has convened with the AIDS United PPC, legal and data privacy experts from the American Civil Liberties Union and the Surveillance Technology Oversight Project, with NASTAD members and staff, public health officials, and community coalitions. Throughout these conversations, it has been made clear that the dangers of law enforcement accessing public health data are not hypothetical or overblown. Public health officials working at state health departments have themselves acknowledged they have little recourse but to release data to law enforcement should one arrive with a discoverable device such as a court order or subpoena.

<sup>1</sup> See AIDS United Public Policy Council, "Position Statement on the Use of Molecular Surveillance to Track HIV Transmission Networks," adopted June 2016, <https://www.hivlawandpolicy.org/sites/default/files/AIDS%20United%20Molecular%20Surveillance%20Statement.pdf>.

<sup>2</sup> See AIDS United Public Policy Council, "CDC NOFO Process and Priority Recommendations," adopted June 2022, <https://drive.google.com/file/d/14PRDAEQWPZjCMUzsySMND5VWGpppaZl/view?usp=sharing>.

CDC resources, including its 2011 *Data Security and Confidentiality Guidelines* makes exceptions for the release of public health information “where required by law.”<sup>3</sup> The recent *HIV Criminalization Legal and Policy Assessment Tool* paints a bleak picture: the landscape of policies either mandating or authorizing the release of data to law enforcement is uneven.<sup>4</sup> State law either “permits” discretion for public health officials in deciding whether and how to share data with law enforcement, or forces them to share the data. However, we must stress that a health department’s “discretion” is no replacement for concrete, legal protections unconditionally prohibiting the release of public health data to law enforcement and immigration enforcement.

The murky patchwork of law and policy that leaves the door open for the use of public health and medical data in prosecutions against PLHIV is further underscored by NASTAD’s “U.S. HIV Data Protection Landscape.” This tool demonstrates the extent to which HIV data can be obtained by law enforcement—sometimes even without so much as a court order. According to NASTAD, 33 states allow HIV data to be accessed by courts, law enforcement, and prosecutors.<sup>5</sup> Only about half of those states require a court order for the release of HIV data. This lack of data protection occurs within a legal system where judges with minimal education about HIV science continue the legacy of biases against Black and brown people in HIV criminal prosecutions.<sup>6</sup>

The expansiveness of HIV criminalization is an important consideration to foreground in the work PACHA, CDC, and ONAP must do to better protect and honor the human dignity of the communities you serve. While 30 states either have an HIV-specific criminal law and/or HIV-related sentence enhancement, 25 states have also used the general criminal law to arrest, prosecute, and imprison PLHIV.<sup>7</sup> That leaves only 10 states without any known history of using the criminal legal system to punish PLHIV. CHLP has tracked some prosecutions, and we have observed an endless procession of cases: reckless endangerment, aggravated assault, assault with a deadly weapon, and even attempted murder—prosecutions all heavily based on someone’s HIV status as the aggravating factor for felony-level imprisonment. While some

<sup>3</sup> The Centers for Disease Control and Prevention (CDC), *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action*, p. 22, (2011), <https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>.

<sup>4</sup> CDC, *HIV Criminalization Legal and Policy Assessment Tool: Legal, Health, and Equity Considerations Related to HIV Criminalization, Public Health Surveillance, and Data Privacy*, p. 24 (2023), <https://www.cdc.gov/hiv/pdf/policies/law/hiv-criminalization-legal-and-policy-assessment-tool.pdf>.

<sup>5</sup> National Alliance of State and Territorial AIDS Directors (NASTAD), “U.S. HIV Data Protection Landscape,” last updated March 2023, <https://nastad.org/resources/hiv-data-protection-landscape>.

<sup>6</sup> Black Americans are more likely to be arrested and convicted in HIV criminal prosecutions. Where state law also severely punishes sex workers living with HIV, Black women are overrepresented in criminal incidents. See The Williams Institute, UCLA School of Law, “HIV Criminalization and Race,” 2019, <https://williamsinstitute.law.ucla.edu/wp-content/uploads/HIV-Crim-and-Race-Infographic.pdf>.

<sup>7</sup> The Center for HIV Law & Policy (CHLP), Map: *HIV Criminalization in the United States: An Overview of the Variety and Prevalence of Laws Used to Prosecute and Punish People Living with HIV in the US*, last updated 2022, <https://www.hivlawandpolicy.org/sites/default/files/HIV%20Criminalization%20in%20the%20US%2C%20CHLP%20062822.pdf>.

states have reformed or repealed their HIV criminalization laws, many states have expanded the scope of prosecution, or retained stigmatizing, severe felony-level penalties.<sup>8</sup> Proposals to expand HIV/STI criminalization are introduced every year in state legislatures across the country, and some “reform” legislation has left critical groups, like sex workers, behind.<sup>9</sup>

Despite recent suggestions from CDC and federal partners on how the state-level HIV data privacy landscape is out of their control, we firmly believe that PACHA, ONAP, and CDC can do more. The CDC has a unique responsibility to address this problem they created by issuing a mandate for every state and jurisdiction to collect, report, and analyze data<sup>10</sup> that can be used in prosecutions against PLHIV without ensuring concrete protections are in place first. In 1999, the CDC established a deadline after which federal funding would be conditioned on whether states followed their recommendations on name-based reporting.<sup>11</sup> Today, we urge PACHA, ONAP, and CDC to take similar action and recommend all CDC grantees establish administrative codes prohibiting the release and/or use of *all public health data* in criminal, civil, and immigration proceedings. Many state health departments have the capacity to issue legislative requests on regulatory and policy needs, and all have the opportunity to testify in legislative hearings. PACHA, CDC, ONAP, and other federal partners should identify and engage every lever that can be pulled in order to secure these overdue public health data protections.

A vulnerable and dangerous HIV and public health data environment threatens public health and undermines public trust in our national and state-level work to end the HIV epidemic. Public health is fundamentally about protecting communities. We need federal leadership and PACHA to recommend policies to make people safe and protected *first*, not as an afterthought.

Washington, DC set an example on which CDC can build upon in its recommendations for NOFO grantees, by passing the HIV/AIDS Data Privacy Protection Amendment Act into law, preventing the release of HIV data for criminal and civil cases in the District of Columbia courts.<sup>12</sup>

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<sup>8</sup> See CHLP, *Timeline of State Reforms and Repeals of HIV Criminal Laws: states with most significant changes to their HIV laws*, last updated 2022, [https://www.hivlawandpolicy.org/sites/default/files/Timeline%20of%20State%20Reforms%20and%20Repeals%20of%20HIV%20Criminal%20Laws%20062822\\_0.pdf](https://www.hivlawandpolicy.org/sites/default/files/Timeline%20of%20State%20Reforms%20and%20Repeals%20of%20HIV%20Criminal%20Laws%20062822_0.pdf).

<sup>9</sup> Molly Minta, “Florida’s HIV Criminalization Laws Target Sex Workers. A Reform Bill Offers Little Relief,” *The Appeal*, Feb 28, 2020, <https://theappeal.org/florida-hiv-criminalization/>.

<sup>10</sup> CDC, “Funding Opportunity Announcement (FOA) PS18-1802: Integrated Human Immunodeficiency Virus (HIV) Surveillance and Prevention Programs for Health Departments,” <https://www.cdc.gov/hiv/funding/announcements/ps18-1802/index.html>.

<sup>11</sup> CDC, “CDC Guidelines for Improved Data on U.S. HIV Epidemic: New Systems Urgently Needed to Guide Prevention Efforts,” December 1999, <https://www.cdc.gov/media/pressrel/hivreprefct3.pdf>.

<sup>12</sup> The Council of the District of Columbia, “HIV/AIDS Data Privacy Protection Amendment Act,” <https://lims.dccouncil.gov/Legislation/B24-0207>.



The communities whom we and PACHA serve are increasingly facing threats of violence, criminalization, and politicized attacks, while their legal rights are being undercut by courts and legislatures every day. The vulnerability of HIV and public health data, combined with unrelenting HIV criminal arrests and prosecutions, and the consistent erosion of public trust in the CDC, have created a perilous foundation upon which our public health infrastructure stands. We hope PACHA, and your federal partners including ONAP and CDC, can take accountability and do everything in your power to remedy the situation before what fragile trust in public health that still exists is further diminished.

Sincerely,

S. Mandisa Moore-O'Neal, Esq.  
Executive Director

Amir Sadeghi  
National Policy and Partner Strategist

Kae Greenberg, Esq.  
Staff Attorney

CHLP

## American Pharmacists Association



April 5, 2023

[Submitted electronically to [PACHA@hhs.gov](mailto:PACHA@hhs.gov)]

Marlene McNeese  
John Wiesman, Dr.P.H., MPH  
Co-Chairs  
Presidential Advisory Council on HIV / AIDS  
Department of Health and Human Services  
Room 800  
Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201.

### RE: PACHA-to-the-People community engagement session

Dear Co-Chairs McNeese and Wiesman:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Presidential Advisory Council on HIV/AIDS (PACHA) on the pharmacists' role in increasing access to HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Pharmacists make up the third largest health care profession and have the second most training behind physicians, graduating with a Doctor of Pharmacy (PharmD) degree. Some pharmacists pursue additional training through one to two-year postgraduate pharmacy residency programs. With extensive training in the properties and appropriate use of medications, their application to acute and chronic disease management, and prevention and wellness services, pharmacists provide a variety of primary health care services, in coordination and collaboration with others in their communities. These services include: chronic condition management where medications are a treatment modality; medication management services – optimizing medication regimens and addressing medication safety issues; coordinating medications during care transitions; providing patient education; delivering prevention and wellness services, including vaccinations and health screenings; conducting point-of-care testing; and treating minor illnesses, where authorized.

As one of the most accessible and trusted health care providers in their communities,<sup>1</sup> pharmacists have a significant role to contribute in initiating access to HIV PrEP/PEP and providing culturally competent and culturally sensitive care. Nearly 90% of the U.S. population lives within five miles of a community pharmacy and this high level of accessibility allows pharmacists to serve in a unique role as another point of entrance for patients to get integrated into longitudinal and acute HIV preventative services. Programs allowing pharmacists

<sup>1</sup> Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I. Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, Journal of the American Pharmacists Association (2022), doi: <https://doi.org/10.1016/j.japh.2022.07.003>.

to furnish an initial supply of HIV PrEP/PEP and then refer patients to longitudinal care provided by community-based organizations and primary care providers have expanded across the country in the past ten years. Leveraging the current health care workforce, including pharmacists, is a key component of the National HIV/AIDS Strategy.<sup>2</sup>

#### **Thematic overview of programs allowing pharmacists to furnish HIV PrEP/PEP**

##### *HIV PrEP*

Pharmacists in community settings are serving to initiate an initial supply of HIV PrEP, following appropriate negative point-of-care tests, and then referral to community-based organizations and primary care providers for longitudinal care. Pharmacists serve as a point of triage, established within accessible and familiar community settings, for patients to enter into the HIV preventative care system. The pharmacists routine engagement in medication counseling and adherence assessment also promotes the pharmacist role in PrEP management given the required patient adherence for the effectiveness for PrEP as HIV prevention.

Many of the programs set specific limits on the days' supply of initial HIV PrEP orders that pharmacists prescribe. Additionally, programs often require pharmacists to inform the patients' primary care provider of the initiation of HIV PrEP within a specific timeframe.

##### *HIV PEP*

Pharmacists in community settings are serving to initiate HIV PEP following a potential exposure within the past 72 hours. The time sensitive nature required for the initiation of medication therapy for PEP makes pharmacist access a pivotal role in HIV prevention. Primary care access for many remains a barrier which increases delays in care and increasing likelihood of viral transmission for those exposed. Pharmacists are often able to prescribe a 28-day regimen; however, in some programs the pharmacist is limited to prescribing a shorter regimen and the patient is referred to another health care professional for the remainder of their PEP regimen. Similar to HIV PrEP programs, pharmacists are often required to inform the patients' primary care provider of the initiation of HIV PEP within a specific timeframe. Engagement through PEP pharmacy services also establishes a contact point for the transition from PEP to PrEP for continued high-risk patients, as recommended by the most recent guideline recommendations by the U.S. Public Health Service, allowing for a more seamless entry into the HIV preventative care system previously mentioned.<sup>3</sup>

Pharmacists have the authority to initiate HIV PrEP in 10 states<sup>4</sup> and HIV PEP in 13 states,<sup>5</sup> via a statewide protocol, standing order, or independent prescriptive authority. As of the time of writing, 11 states<sup>6</sup> are considering expanding access pharmacist provided HIV PrEP/PEP through bills in state legislatures during the 2023 sessions.

The establishment and success of such programs is dependent on overcoming two primary policy barriers, pharmacists' state scope of practice, and coverage for pharmacists' patient care services by Medicare Part B, Medicaid, and commercial health plans.

#### **Pharmacists' scope of practice to furnish HIV PrEP/PEP**

Pharmacists' scope of practice has grown substantially across the country over the last 25 years, unlocking an array of new opportunities for pharmacists to provide added services and value to patients while working as an equal member of an interprofessional and collaborative healthcare team. Pharmacists' foundational scope of practice traditionally has been limited to making medication therapy recommendations that require prescriber approval to make medication changes. Through expanded authorities, pharmacists can use their medication expertise to autonomously prescribe medications through various mechanisms.

<sup>2</sup> The White House. 2021. National HIV/AIDS Strategy for the United States 2022–2025. Washington, DC.

<sup>3</sup> Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published 2021.

<sup>4</sup> Arkansas, California, Colorado, Idaho, Illinois, Maine, Nevada, Oregon, Utah, Virginia

<sup>5</sup> Arkansas, California, Colorado, Idaho, Illinois, Maine, Missouri, Nevada, New Mexico, New York, Oregon, Utah, Virginia

<sup>6</sup> California, Connecticut, Florida, Maryland, Massachusetts, Minnesota, Missouri, Montana, New Jersey, New York, Rhode Island



Pharmacists' prescriptive authority is variable from state-to-state and falls on a spectrum of how independently they may prescribe. This is often completed through collaborative arrangements with physicians, nurse practitioners, physician assistants, or other prescribing practitioners. In recent years, there has been an expansion in pharmacists' ability to provide services in response to public health needs and disease states (examples include HIV PrEP/PEP, hormonal contraceptives, tobacco cessation, and naloxone). Many of these services are provided by pharmacists under statewide protocols or standing orders.

#### **Payment for pharmacists' services associated with the furnishing of HIV PrEP/PEP**

As stated in the National Academies of Sciences, Engineering, and Medicine (NASEM) report, "The greatest challenge to integrating the role of the pharmacist in primary care relates to financing barriers..."<sup>7</sup> Pharmacists and their services are not currently recognized in Medicare Part B, and coverage is variable in state Medicaid and private sector plans indicating inequitable access to coverage of pharmacist-provided patient care services. Lack of payment to cover the pharmacist's time to deliver professional services is a significant barrier that must be addressed to fully utilize pharmacists as medication experts. Another barrier related to sustainable models for pharmacists' services is in value-based payment models. While APhA supports these models, many are still dependent on fee-for-service (FFS) payment as a component, and the lack of FFS payment for pharmacists further complicates their involvement. In addition, pharmacists' documentation of patient care data is often not accepted or attributed in quality metric calculations, preventing their contributions to care from being fully recognized in these models.

H.R. 1770, the Equitable Community Access to Pharmacists Services (ECAPS) Act would amend title XVIII of the Social Security Act to provide coverage of certain services by pharmacists under Medicare Part B.<sup>8</sup> Additionally, there are numerous efforts at the state level to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of their services under the medical benefit through the submission of a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) by state medical assistance programs.

#### **Other barriers to implementation**

*Pharmacist workplace conditions:* As early as the 1980s<sup>9,10</sup>, articles were published describing pharmacist and pharmacy personnel working conditions and burnout. The practice of pharmacy has evolved since those initial articles were published, but workforce issues continue to permeate pharmacy practice settings. Pharmacists are highly trained medication experts providing accessible<sup>11</sup> direct patient care and medication distribution nationwide in all geographical areas to under-/uninsured,<sup>12</sup> commercially insured, and Medicaid/Medicare eligible patients. Pharmacists and pharmacy personnel clearly demonstrated their essential role in our communities throughout the COVID-19 pandemic by administering 300+ million COVID-19 vaccines, conducting 42+ million COVID-19 tests, and contributing to billions of dollars in savings.<sup>13,14</sup> To address pharmacist workplace conditions, and, in order to leverage pharmacists to their full potential as a part of an interprofessional and collaborative health care team, there is a need to align their scope of practice with their education and training and cover pharmacists' services under the medical services side of Medicare Part B, and the medical benefit of state Medicaid programs and commercial health plans.

*Health information technology access:* Another barrier for some pharmacists, especially those in community pharmacies, is electronic health record (EHR) access and the ability to send and receive clinical information needed for providing patient care. A salient example is FDA's recent authorization of pharmacists to prescribe the COVID-19 antiviral, Paxlovid with certain limitations.<sup>15</sup> Pharmacists must have access to lab values to review a patient's renal status before prescribing Paxlovid. Having EHR access to this information would

<sup>7</sup> National Academies of Sciences, Engineering, and Medicine. 2021. Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25983>.

<sup>8</sup> <https://www.congress.gov/bills/118th-congress/house-bill/1770/text>

<sup>9</sup> [https://doi.org/10.1016/S0160-3450\(16\)32767-2](https://doi.org/10.1016/S0160-3450(16)32767-2)

<sup>10</sup> [https://doi.org/10.1016/S0160-3450\(16\)31647-6](https://doi.org/10.1016/S0160-3450(16)31647-6)

<sup>11</sup> <https://pharmacist.com/Advocacy/Issues/Inequity-to-COVID-19-Test-to-Treat-Access-Pharmacists-can-help-if-permitted>

<sup>12</sup> <https://www.pharmacist.com/Publications/Pharmacy-Today/Article/serving-underserved-populations>

<sup>13</sup> <https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19/Infographic>

<sup>14</sup> <https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19>

<sup>15</sup> Food and Drug Administration. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Available at: <https://www.fda.gov/media/155050/download>.

greatly streamline service delivery and help provide timely access to this medication for eligible patients. Access to this information could facilitate more efficient delivery of HIV PrEP/PEP to patients in community pharmacy settings to allow pharmacists to review patient's renal status, viral status, and hepatitis B status necessary for clinical eligibility and proper management as recommended by the 2021 PrEP Clinical Practice Guideline for HIV Prevention by the U.S. Public Health Service.<sup>16</sup>

Thank you for the opportunity to provide these comments in support of PACHA. Pharmacists play a vital role in providing HIV preventative care services, and through removal of barriers and federal and state action, can be further optimized in contributing to these vital health care services. Given the significant opportunity that pharmacists have to play with the removal of these barriers, APhA recommends the following to PACHA:

- We recommend that the focus of the next PACHA Meeting be focused on Objective 1.4 of the National HIV/AIDS Strategy, specifically on expanding “the number, variety, diversity, and distribution of health care providers who routinely provide HIV testing, prevention counseling, and linkage to specialty care” and Box 6, “Pharmacists’ Roles in HIV Prevention and Care”.
- There is not currently a pharmacist member of PACHA. Given the pharmacists’ role in HIV prevention and care, we recommend that a pharmacist be added as a member of PACHA. We feel strongly that a pharmacist representative is needed at the table to appropriately advise and expand access to pharmacist-provided HIV preventative care services.

APhA would welcome the opportunity to work with PACHA on the implementation of these two recommendations, including identifying a pharmacist expert to serve as a member of PACHA. If you have any questions or require additional information, please contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs at [mmurphy@aphanet.org](mailto:mmurphy@aphanet.org).

Sincerely,



Brigid K. Groves, PharmD, MS  
Vice President, Pharmacy Practice  
American Pharmacists Association

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<sup>16</sup> Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published 2021.

# **The Center for HIV Law and Policy, Prep4all, The Positive Women’s Network, and Patient Privacy Rights Foundation**

COMMENTS OF THE ELECTRONIC PRIVACY INFORMATION CENTER, THE CENTER  
FOR HIV LAW AND POLICY, PREP4ALL & THE POSITIVE WOMEN’S NETWORK +,  
PATIENT PRIVACY RIGHTS FOUNDATION

to the

Health and Human Services Department

on

System of Records Notice, System No. 09-90-2101 HIV Prevention Medication Distribution  
Records

88 Fed. Reg. 3,999

February 22, 2023

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The Office of Infectious Disease and HIV/AIDS Policy (OIDP) is proposing to establish a new database to help Gilead Pharmaceuticals verify identity and eligibility of enrollees in a joint program between Gilead and OIDP to distribute Pre-Exposure Prophylaxis (PrEP) to people at high risk of contracting HIV.<sup>1</sup> The proposed database would collect and maintain a variety of personal information and healthcare records from multiple vulnerable populations.

CHLP is a national legal and policy thinktank fighting stigma and discrimination at the intersections of HIV, race, health status, disability, class, sexuality and gender identity, and expression—with a focus on the criminal legal system and the public health system. We do this through legal advocacy, high impact policy initiatives and the creation of cross-issue partnerships, networks and resources.

Founded in March 2018, PrEP4All is an organization of community members, healthcare professionals, lawyers, and academics all dedicated to increasing access to lifesaving HIV medication. Every member of PrEP4All has been personally affected by the HIV epidemic, and most of us rely on HIV medications every day.

The Electronic Privacy Information Center (“EPIC”) is a public interest research center in Washington, D.C., established in 1994 to focus public attention on emerging civil rights and liberties issues. EPIC regularly submits regulatory comments and amicus briefs in cases involving threats to Americans’ health privacy.

Positive Women’s Network-USA (PWN) is a national organization building power by and for women, trans and gender non-binary people living with HIV, with a focus on those communities most impacted by the epidemic. PWN’s work is grounded in social justice and

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<sup>1</sup> 88 Fed. Reg. 3,999.

human rights, and we explicitly apply a racial justice and gender justice lens to address the many, intersecting barriers people living with HIV face.

Patient Privacy Rights' purpose is to honor and empower the individual's right to privacy through personal control of health information wherever such information is collected and used. PPR educates, collaborates and partners with people to ensure privacy in law, policy, technology, and maximize the benefits from the use of personal health information with consent.

The undersigned groups writing represent people in the vulnerable populations most likely to be affected by the database, HIV policy experts, and privacy experts. We urge ODP not to implement this database and to instead follow established protocols for distributing medication without overly burdensome eligibility requirements or the threat of unnecessary surveillance primarily in order to further Gilead Sciences' corporate interests with no public health benefit. This database creates substantial and unnecessary risks to the privacy and safety of already marginalized people vulnerable to contracting HIV. ODP decided to implement the database without consulting the relevant HIV policy and privacy advocates. Creating high barriers to access free PrEP and tying associated PrEP distribution programs to overly broad surveillance will discourage enrollment, working against this program's public health goals. This program could undermine larger and more impactful interventions including a nationwide PrEP program.

### **Background**

Despite the invention of highly effective drugs to prevent the transmission of HIV more than ten years ago, HIV continues in the United States. In 2019, the most accurate recent reference year, 36,940 people were diagnosed with HIV in the US.<sup>2</sup> In total, HIV has taken more than half a million lives in the U.S.<sup>3</sup> Although people across demographics contract HIV, new infections are most common among gay and bisexual men, transgender women, Black and Hispanic/Latino people, and younger people.<sup>4</sup> These same populations are disproportionately marginalized due to poverty, racism, homophobia, transphobia, immigration status, unequal access to benefits, and stigma. In short, the people who need PrEP the most tend to have the fewest resources and bear the highest burdens in society.

In 2015, the CDC estimated that between 1.2 and 1.8 million people have indications that would warrant taking PrEP, but that year only 6% of them actually had prescriptions.<sup>5</sup> By 2020, only 25% of those most in need of PrEP were estimated to have received a prescription with staggering racial and ethnic disparities: 66% of White individuals most in need of PrEP had

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<sup>2</sup> Centers for Disease Control and Prevention, *HIV Surveillance Report* (2020), <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>.

<sup>3</sup> Centers for Disease Control and Prevention National Center for Health Statistics, *HIV in the U.S. by the Numbers*, cdc.gov (Aug. 26, 2022), <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/hiv-in-the-us-by-the-numbers.html>.

<sup>4</sup> Centers for Disease Control and Prevention, *HIV Surveillance Report* (2021).

<sup>5</sup> Dawn K. Smith et al., *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015*, 65 *Morbidity & Mortality Weekly Rep.* 1291, 1291–95 (2015).

access while only 9% of Black and 16% of Latinx individuals had received a prescription.<sup>6</sup> The failure to broadly provide PrEP to individuals vulnerable to HIV has been described as “one of the greatest public health implementation failures in the history of this country.”<sup>7</sup> Although generic-brand PrEP is available in many countries for as little as \$6 month, in the U.S. the cash cost of PrEP (Truvada) can approach \$2,000 per month.<sup>8</sup> Making PrEP broadly available for vulnerable populations is an urgent part of the federal government’s End the HIV Epidemic in the US (EHE) strategy.<sup>9</sup> The overarching goal of that program is to reduce new cases of HIV by 90% by 2030. Part of that strategy is implemented through the Ready, Set, PrEP (RSP) initiative.

In 2019, Gilead, the manufacturer of PrEP medications emtricitabine/tenofovir disoproxil fumarate and emtricitabine/tenofovir alafenamide, agreed to donate PrEP to up to 200,000 individuals each year through a partnership with ODP resulting in the establishment of RSP.<sup>10</sup> Gilead maintains a separate program called Advancing Access which also provides some individuals with free or low-cost access to PrEP.<sup>11</sup> RSP has been largely unsuccessful: despite an ambitious target of 10,000 enrollees in its first year, RSP had only provided access to PrEP for a mere 800 individuals by June 2020. Much of this failure is because RSP is largely duplicative of Advancing Access. Enrollment requirements are nearly identical between the two programs, and both act exclusively as a medication distribution program and not a comprehensive access program, which would also address costs related to necessary HIV testing, quarterly and annual lab work, and provider visits.<sup>12</sup>

This System of Records Notice is the latest implementation of Gilead’s partnership with HHS to donate PrEP through the Ready, Set, PrEP program. To determine initial eligibility to receive PrEP, the system will collect:

“patient name, date of birth, location, and the last four digits of the patient's Social Security Number; name and address of prescribing practitioner and practice location; the patient's certification that the patient is not covered by a health

<sup>6</sup> See Centers for Disease Control and Prevention, *PrEP for HIV Prevention in the US* (2022), available at <<https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/prep-for-hiv-prevention-in-the-us-factsheet.html>>.

<sup>7</sup> The PrEP4All Collaborations, *A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States*, 22nd Int’l AIDS Conference (Jul. 2018), <https://static1.squarespace.com/static/5e937afb7d7a75746167b39c/t/5ea5ff68ccd2820f98798d1f/1587937130060/A+National+Action+Plan+for+Universal+Access+to+HIV+Pre-Exposure+Prophylaxis+%28PrEP%29.pdf>.

<sup>8</sup> *Id.* at 21; Kristen Gerencher, *5 Ways to Save on PrEP Costs (With or Without Insurance)*, GoodRx (Aug. 25, 2022), <https://www.goodrx.com/truvada/truvada-hiv-prep-cost-generic-how-to-save> (based on recent GoodRx market research).

<sup>9</sup> 88 Fed. Reg. 3,999.

<sup>10</sup> See Presidential Advisory Council on HIV/AIDS (PACHA) 65th Meeting at 4 (Oct. 21-22, 2019), available at <https://files.hiv.gov/s3fs-public/PACHA-65th-Full-Council-Meeting-Summary.pdf>.

<sup>11</sup> See e.g., Gilead, *Gilead’s Advancing Access Program Is Here to Help You* (2023), <https://www.gileadadvancingaccess.com>.

<sup>12</sup> Chris Sloan et al., *PACHA Highlights Need to Address HIV PrEP Coverage Disparities*, Avalere (Apr. 7, 2021), <https://avalere.com/insights/pacha-highlights-need-to-address-hiv-prep-coverage-disparities>.



insurance plan or policy that covers outpatient prescription drugs; and the patient's consent to information sharing between OASH/OIDP, its contractor, the Product manufacturer, and the patient's prescribing health care provider... Demographic information (race, ethnicity, gender identity, and sex assigned at birth) will be included in both application records and enrolled patient records.”<sup>13</sup>

Meanwhile for continuing eligibility the system will house details of patients medical history including:

“twice yearly confirmations of the patient's continued eligibility (e.g., negative HIV status based on quarterly HIV tests) from the patient's prescribing health care provider; amount of Product dispensed to the patient, reported by the participating pharmacy; and periodic re-certification(s) from the patient attesting that the patient is not covered by a health insurance plan or policy that covers outpatient prescription drugs.”<sup>14</sup>

Patients will need to register when they enroll in the program. Patients and their doctors are expected to periodically submit updates to maintain eligibility. The database will not simply house patient records, but also require regular updates including reporting of quarterly HIV test results. HHS anticipates having at least two separate contractors with access to the database, as well as Gilead staff and government employees.<sup>15</sup>

**I. The proposed database creates substantial and unnecessary privacy risks in order to further Gilead’s business interests.**

Privacy is a serious concern for many people taking PrEP, particularly those from marginalized communities, because it is a prerequisite for their safety. A distribution program like this one risks doing more harm than good if it unnecessarily sacrifices patients’ privacy in the present and exposes patients to potential harms in the future. A federally run database accessible by multiple actors and holding sensitive health information creates privacy risks that cannot be mitigated. In addition, the scheme HHS and Gilead are proposing collects substantially more information than is necessary, magnifying the risks to already vulnerable populations.

**a) The existence of this database is an unnecessary privacy and safety risk for marginalized people.**

Data collection and storage is often a necessary part of administering a federal program or monitoring progress on key public health initiatives. However, such collection should only be done when necessary for the administration of the program and should be balanced against the substantial criminal and societal vulnerabilities experienced by marginalized communities most in need of PrEP.

The unfortunate reality created by outdated HIV criminal laws is that data that identifies individuals can expose them to targeted prosecution, discrimination, stigma, and interpersonal

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<sup>13</sup> 88 Fed. Reg. 4000.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

violence. At least 35 states have laws that criminalize actions potentially exposing another person to HIV.<sup>16</sup> These laws do not focus on a specific intent to transmit HIV or even require that HIV transmission has occurred, but instead focus on the very broad, very vague concept of exposure—even for no- to low-risk sexual activity. In this climate, community advocates are reasonably concerned that maintaining an overly detailed and widely accessible database of people at high risk for contracting HIV could become a short-list for police and prosecutors looking to further criminalize this population and increase the risk of wrongful arrest. Furthering Gilead’s business interests does not constitute a reasonable circumstance to exacerbate these fears and undermine community trust.

The conditions that require careful consideration of any new database extend beyond HIV criminalization. HIV status and vulnerability to HIV acquisition is also a significant driver of employment discrimination in the U.S. The Equal Opportunity Employment Commission records dozens of violations of employment law from businesses discriminating against individuals with HIV annually and in recent years has averaged well over half a million dollars in restitution awarded.<sup>17</sup> The EEOC’s investigations are on top of investigations under state and local anti-discrimination law and reflect only a fraction of all cases.

This proposal to create a database of PrEP users also intersects with how racism, namely criminalization and policing, is a huge threat to public health. We must locate the call for this database in its appropriate political context: the increased surveillance and continued policing of Black and Brown communities as a direct result of bipartisan support for heightened law enforcement budgets despite decreased safety and quality of life. ODP must ask itself: considering the data on who is most vulnerable to HIV, how do more barriers to PrEP align with the Ending the Epidemic goals?<sup>18</sup> If these public and private entities are truly invested in ending HIV, how does a forced registry encourage people to sign up for PrEP or other health care?

Based on collective histories and current realities of surveillance and policing not only from law enforcement but also from public health officials and departments, there is a well-founded lack of trust. These initiatives grow that distrust instead of repairing it. When deeply marginalized communities see an opportunity for further surveillance and criminalization, they will rightfully move away from it, even when tied to health care. This is especially concerning when there are better options available that will incentivize, not disincentivize, access to PrEP. A system like the one proposed here sends a message to deeply marginalized communities, namely working-class Black and Brown people, that policymakers do not understand their concerns.

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<sup>16</sup> CDC, HIV and STD Criminalization Laws (Oct. 24, 2022), <https://www.cdc.gov/hiv/policies/law/states/exposure.html> (noting “After more than 40 years of HIV research and significant biomedical advancements to treat and prevent HIV transmission, many state laws are now outdated and do not reflect our current understanding of HIV.”)

<sup>17</sup> Equal Employment Opportunity Commission, *ADA Charge Data—Monetary Benefits (Charges filed with EEOC) FY 1997 - FY 2021*, <https://www.eeoc.gov/data/ada-charge-data-monetary-benefits-charges-filed-eeoc-fy-1997-fy-2021>.

<sup>18</sup> ODP, *What Is Ending the HIV Epidemic in the U.S.?* (Jul. 1, 2022), <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

Certain contemporary political sentiments also show that now is a particularly poor time for HHS to further Gilead's interests by creating this database. Risk of HIV status is a proxy for disproportionately targeted demographics including LGBTQ+ individuals, Black and Brown individuals, immigrants, and those most marginalized by poverty. Potential enrollees in a PrEP program will be rightly concerned that a list of individuals receiving PrEP could easily become a list of easy targets for a state or federal administration hostile to gay and trans rights, BIPOC people, and the poor. This database cannot be understood outside the context of other registries explicitly targeting LGBTQ+ people. For example, the state of Texas recently moved to compile a record of all transgender people who had changed their names on drivers' licenses in the state.<sup>19</sup> 2022 set a record for the most anti-transgender bills introduced in state legislatures, and this year more have been filed in the first two months than in all of last year.<sup>20</sup> The decision to mandate collecting and compiling sensitive personal information for individuals to access life-saving care must be understood not in a policy vacuum, but in a landscape that is increasingly hostile to many of the people who will be in this database.

The risk of data abuse or data breach is not hypothetical, but a serious safety concern. Data breaches are both increasingly common and increasingly severe. As an example of this trend across the federal government, a 2015 data breach at the Office of Personnel Management (OPM) exposed social security numbers and other personal data from 21.5 million individuals.<sup>21</sup> Around the same time, OPM reported another major data breach exposing records on about 4 million federal employees.<sup>22</sup> Just a year before, a breach at the U.S. Postal Service led to the loss of personal information from more than 800,000 employees.<sup>23</sup>

The greatest risks of data breaches come from the government holding large volumes of personal information that can have lasting financial and security impacts when wrongfully divulged. For example, The Federal Emergency Management Agency (FEMA) unnecessarily disclosed sensitive information from victims of the 2017 California wildfires, exposing up to 2.3 million people.<sup>24</sup> FEMA shared details of victims' financial institutions and personal lives, including EFT and bank transit numbers and complete addresses.<sup>25</sup> While traditionally the focus

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<sup>19</sup> Kylie Cheung, *Texas Creates Chilling Registry of 16,000 People Who Changed Genders on Their Driver's Licenses*, Yahoo! News (Dec. 15, 2022), <https://news.yahoo.com/texas-creates-chilling-registry-16-181000674.html>.

<sup>20</sup> James Factora, *Over 300 Anti-LGBTQ+ Bills Have Already Been Filed in 2023*, Teen Vogue (Feb. 13, 2023), <https://www.teenvogue.com/story/anti-lgbtq-bills-filed-2023>.

<sup>21</sup> U.S. Gov't Accountability Office, *DHS Needs to Enhance Capabilities, Improve Planning, and Support Greater Adoption of Its National Cybersecurity Protection System* (Jan. 2016) at 8, <https://www.gao.gov/assets/680/674829.pdf>.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Cybersecurity and Infrastructure Security Agency, *Federal Agency Compromised by Malicious Cyber Actor*, AR20-268A, Dep't. of Homeland Sec. (Sept. 24, 2020), <https://us-cert.cisa.gov/ncas/analysis-reports/ar20-268a>; Duncan Riley, *DHS discloses data breach of US agency but doesn't name which was hacked*, SiliconAngle (Sept. 24, 2020), <https://siliconangle.com/2020/09/24/dhs-discloses-data-breach-us-agency-doesnt-name-hacked/>.

<sup>25</sup> Christopher Mele, *Personal Data of 2.3 Million Disaster Victims Was Released by FEMA, Report Says*, N.Y. Times (Mar. 22, 2019), <https://www.nytimes.com/2019/03/22/us/fema-data-breach.html>; John V.



on protecting federal agency databases has settled on improving cybersecurity practices, implementation of best practices has been uneven at best. In 2018 for example, the GAO found that over 700 of its cybersecurity recommendations since 2010 had not been implemented by federal agencies.<sup>26</sup> And just this year a new GAO report revealed that more than 60 percent of the agency's privacy recommendations have not been adopted by federal agencies.<sup>27</sup> Holding sensitive personal information will inherently create risks of abuse, accidental disclosure, and data breach.

The risk of data breach can also be a barrier to providing medical care because there is an established track record of data breaches specifically impacting individuals vulnerable to HIV. On February 10, 2023, Lambda Legal announced a settlement for data breaches in the enrollment program for California's AIDS Drug Assistance Program. In 2018, Aetna settled a lawsuit for accidentally revealing that people were taking PrEP and other HIV medications in the clear window of envelopes.<sup>28</sup> And in 2019, a University of California at San Diego study on the impact of domestic violence, substance abuse and other traumatic events for women with HIV had a substantial data breach exposing extraordinarily confidential information to a broad array of unauthorized staff.<sup>29</sup> These breaches show that privacy harms are increasingly possible for programs meant to benefit persons living with and vulnerable to HIV, and that there are substantial real and perceived risks to collecting and maintaining this data, particularly if it exists primarily to appease corporate interests with no compelling public or individual health benefit.

**b) The details of this data collection scheme are overly invasive and do not meet privacy best practices standards.**

Best practices for privacy include data minimization and limiting access to only necessary actors through purpose specification and use limitation.<sup>30</sup> The proposed database fails to meet those standards by collecting more information than is necessary and inserting more actors than are necessary under other schemes.

Data minimization requires collecting only directly relevant and necessary information and deleting that information as soon as possible. This program is unnecessarily invasive because

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Kelly, Management Alert – FEMA Did Not Safeguard Disaster Survivors' Sensitive Personally Identifiable Information, OIG-19-32, Dep't of Homeland Sec. Off. of Inspector Gen. (Mar. 15, 2019), <https://www.oig.dhs.gov/sites/default/files/assets/2019-03/OIG-19-32-Mar19.pdf>.

<sup>26</sup> U.S. Gov't Accountability Office, *GAO-19-105 Information Security: Agencies Need to Improve Implementation of Federal Approach to Securing Systems and Protecting Against Intrusions* (Dec. 18, 2018), <https://www.gao.gov/assets/700/696105.pdf>.

<sup>27</sup> U.S. Gov't Accountability Office, *GAO-23-106443 Cybersecurity High-Risk Series: Challenges in Protecting Privacy and Sensitive Data* (Feb. 14, 2023), <https://www.gao.gov/assets/gao-23-106443.pdf>.

<sup>28</sup> Elana Gordon, *Aetna Agrees To Pay \$17 Million In HIV Privacy Breach*, NPR (Jan. 17, 2018), <https://www.npr.org/sections/health-shots/2018/01/17/572312972/aetna-agrees-to-pay-17-million-in-hiv-privacy-breach>.

<sup>29</sup> Jill Castellano & Brad Racino, *UCSD Has Not Told Women with HIV of Data Breach, Despite Researchers' Pleas*, inewssource (May 14, 2019), <https://inewssource.org/2019/05/14/ucsd-data-breach-hiv-women-study/>.

<sup>30</sup> See Federal Privacy Council, *Fair Information Practice Principles*, <https://www.fpc.gov/resources/fipps/>.

it requires overly intensive verification procedures for doctors and patients. First, the program requires semi-annual renewals instead of annual renewals. Second, the program requires detailed statements of continuing eligibility including actual documentation of negative HIV status and lack of insurance coverage. All of this granular information could be avoided with a simple certification from the prescribing doctor that patients meet the eligibility criteria.

The system also collects population data that is not necessary for verifying identity but could be misused. Alongside the personal information that OIDP will collect to verify identity, the program will also collect demographic data including “race, ethnicity, gender identity, and sex assigned at birth”.<sup>31</sup> Although OIDP intends to use this data for statistical purposes only, including it is not necessary to verify patients’ identities or eligibility. This increases the risk of harm from a data breach. All of these factors may form a basis for discrimination and could be abused to target individuals with violence or wrongful prosecution. Such information should not be housed in patient records held by third parties unless necessary.

The design of this system also exposes data to at least two private contractors, the relevant staff at OIDP, and staff at Gilead, essentially inserting HHS as an intermediary and giving extra parties access to the system. This scheme creates unnecessary risks of breach by expanding who has access to the system and creating the possibility of housing the information on multiple systems. The more locations data is stored, and the more people who have access to it, the greater the risk that sensitive personal information is exposed.

## **II. This database was imposed without consulting impacted persons or expert advocates and runs contrary to public policy.**

The proposed database has been developed without the knowledge and input of impacted persons and unbiased experts. This is unfortunately obvious given the system of records notice (SORN), which leans into instead of avoiding some of the most common pitfalls in administering public health programs for low-income, LGBTQ+ and BIPOC groups vulnerable to acquiring HIV. Quick outreach to other leading national HIV/AIDS organizations appears to confirm this; it seems that no leaders in PrEP access and HIV privacy concerns had heard of the proposed database. More engagement with impacted communities and experts up-front could have resulted in a SORN that needed to be amended; this one will have to be largely scrapped if its public health goals are to be achieved.

Vulnerable people are less likely to seek out PrEP when they fear it will be tied to surveillance, will lead to stigma, or will involve cumbersome and degrading eligibility processes. Studies also show that complex application and eligibility processes like the ones anticipated in this SORN undercut program adoption and adherence. As one uninsured consumer reported in a 2021 focus group, “I stopped using [PrEP] because it became too much of a hassle to keep verifying my information every month. That I didn’t have a job, that I didn’t have income. And it

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<sup>31</sup> 88 Fed. Reg. 4,000.

started making me feel bad.”<sup>32</sup> But this program only feeds into those fears and insecurities by establishing a system of relatively invasive and cumbersome eligibility checks and databases.

As an example, the proposed database may disincentivize program adoption because putative members will justifiably fear surveillance and exposure to law enforcement, particularly given the extensive network of entities that will have access including the Department of Justice. LGBTQ men, especially Black gay, bisexual and men who have sex with men, are at increased risk of having negative encounters with law enforcement officers.<sup>33</sup> This has sparked a culture of fear and psychological distress that has already dampened Black men who have sex with men’s likelihood of obtaining PrEP.<sup>34</sup> For this reason, experts recommend that public health HIV prevention projects avoid involving law enforcement officers and techniques.<sup>35</sup> But this program involves invasive surveillance of putative program members and explicitly states it will share information with the Department of Justice.<sup>36</sup> Although the current provisions for DOJ access are limited, authorizing any law enforcement access creates a potential for abuse and leaves the door open to amend the routine uses to expand that access in the future.

### **III. There are established practices for medication distribution programs that are safer.**

A community-driven eligibility model is a safer and better fit for this program. One such model was proposed as part of a national PrEP program last year.<sup>37</sup> A community-based approach would improve access while reducing privacy risks.

Any registry for PrEP access should be limited to necessary information and only accessible by healthcare providers and pharmacies. Patient providers should be responsible for checking eligibility and adding people to a registry for PrEP access. Identity can be tied to a drivers’ license or other de-duplicated credential. Patients should receive a pseudorandom number identifier that pharmacies can check against the registry to determine eligibility. Such a registry should not be housed by or accessible to HHS. Ultimately, Gilead does not need access to the database either. Gilead’s only claimed need is to verify that patients are not “double dipping” in Ready, Set, PrEP and the company’s Advancing Access program. But this is a problem of Gilead’s own making and the onus should not rest on patients to give up privacy rights to satisfy fraud concerns. A limited sample could be provided to an independent auditor to determine the presence and prevalence of fraud, but access beyond that is unnecessary.

Patients should also have rights to transparency and data removal. Patients should be regularly informed if their information has been accessed. Patient identity should also be blinded

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<sup>32</sup> Amy Killelea *et al.*, *Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic*, 50 J. L., Med. & Ethics 8, 13 (2022).

<sup>33</sup> Center for American Progress & Movement Advancement Project, *Unjust: How the Broken Criminal Justice System Fails LGBT People* 3, 37 (2016).

<sup>34</sup> See Devin English *et al.*, *Intersectional Social Control: The Roles of Incarceration and Police Discrimination in Psychological and HIV-Related Outcomes for Black Sexual Minority Men*, 258 Soc. Sci. & Med. 1, 6 (2020).

<sup>35</sup> *Id.*

<sup>36</sup> See 88 Fed. Reg. 4001.

<sup>37</sup> See Killelea *et al.*, *supra* note 32, at 8–23.

or removed from the database when patients unenroll in the program. A provider-maintained database as described would present fewer privacy risks without compromising functionality.

**IV. The Ready, Set, PrEP program should not take any steps that would impair the effectiveness of a national PrEP access program.**

This would be a particularly inopportune time for HHS to undermine community trust given the current momentum for a National PrEP Program. As part of his FY23 Budget Request, President Biden included a vision for comprehensive national PrEP access, calling for a \$9.8B investment over 10 years. Community advocates and other stakeholders have been galvanized by this proposal, generating thousands of individual and organizational signatures in support. As part of the final FY23 budget, Congress included a call for the Centers for Disease Control and Prevention to address equitable PrEP access.

Such progress would be needlessly threatened were HHS to move forward with a database with seemingly no public health benefit. That such a sacrifice of privacy and trust should come in order to maintain RSP— a duplicative and failed medication distribution mechanism— at a time when a more effective and comprehensive national PrEP access initiative is on the verge of becoming a reality, would be all the more unfortunate.

**Conclusion**

We urge HHS not to go forward with developing and implementing this database. Impacted persons, policy experts, HIV rights advocates, and privacy experts were not consulted on this proposal and suggest alternative measures. Ultimately, this database should be understood in the context of increasing repression for marginalized populations and policy efforts should be closely scrutinized so as not to impair the effectiveness of larger programs in the future.

Sincerely,

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