March 24, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–8016


Dear Administrator Brooks-LaSure:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG), a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. Our organizations welcomed the revised National HIV/AIDS Strategy (NHAS) released by President Biden on December 1, 2021, World AIDS Day. A focus on ending the HIV epidemic fits squarely within the Biden Administration’s priority issues: eliminating racial and ethnic health disparities, increasing access to care, reducing health care costs, and addressing the social determinants of health.

The Centers for Medicare and Medicaid Services (CMS) will play a vital role in the campaign to end the HIV epidemic. Due to efforts by the Biden Administration, more people than ever before have health insurance, including more people living with HIV. In states that have expanded Medicaid, the uninsured rate for people living with HIV has dropped precipitously; today, just 6% of people living with HIV in expansion states remain uninsured, compared to 20% in non-expansion states.1 Additionally, Medicare will play an ever-increasing role in access to care for long-term survivors.2 Because of advancements in antiretroviral treatment, people living with HIV are now aging with HIV well into the golden years. Almost half of the 1.2 million people living with HIV are over 50 years old, with many enrolled in or soon to be enrolled in Medicare.3 Altogether, the health insurance programs under the jurisdiction of CMS play an outsized role in providing health coverage to people living with HIV.

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As CMS develops initiatives focused on addressing racial and ethnic disparities, it must ensure that HIV is a key focus of those efforts. The NHAS goals and objectives are based on extensive data documenting the disparities that increase risk and prevalence of HIV for people in marginalized communities. The impact of HIV on communities of color is stark: In 2019, two-thirds of people living with HIV were Black/African American or Hispanic/Latino, despite making up just under one-third of the U.S. population.\footnote{National HIV/AIDS Strategy 2022-2025, p. 15, https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf.} While two-thirds of white people eligible for PrEP were prescribed it, just 9% of Black people and 16% of Hispanic/Latinx people eligible for PrEP have been prescribed it.\footnote{U.S. Centers for Disease Control and Prevention, \textit{PrEP for HIV Prevention in the U.S.}, November 2021} CMS’ focus on health equity must include policies increasing access to HIV prevention, screening, and treatment for people in communities of color.

Efforts to End the HIV Epidemic in the United States require a strong, unified commitment from agencies across the Administration and must be continuously informed by the community, particularly people living with HIV who come from disproportionately impacted communities.\footnote{Please refer to \textit{Demanding Better: An HIV Federal Policy Agenda by People Living with HIV} by the U.S. People living with HIV Caucus and \textit{Ending the HIV Epidemic in the United States} by AIDS United and ACT NOW: END AIDS for policy guidance.} We urge CMS to ensure that the health insurance programs under its jurisdiction provide coverage commensurate with the standard of care for HIV, and in alignment with the Centers for Disease Control and Prevention (CDC) HIV treatment and prevention guidelines. We also urge CMS to work with states to ensure that Medicaid programs’ policies do not inadvertently or arbitrarily erect barriers that keep people at risk of, or living with, HIV from getting access to the screening, prevention, and treatment they need.

The implementation of the National HIV/AIDS Strategy must also consider the impact that ending the public health emergency will have on people living with or at risk of HIV. The expiration of the public health emergency declaration is expected to result in substantial Medicaid disenrollment.\footnote{It is estimated that about 15 million people will lose Medicaid coverage. M. Buettgens & A. Green, \textit{What will happen to Unprecedented Medicaid Enrollment after the Public Health Emergency?} (September 2021).} The federal implementation plan must take this disenrollment into account and set aside resources to ensure that those eligible for Medicaid are not otherwise disenrolled due to avoidable administrative error. Additionally, those individuals ineligible for Medicaid should be supported when accessing other forms of health care coverage, including financial support on the Marketplace. CMS should work closely with states to ensure that dedicated resources are available in advance of redetermination processes and that progress in getting people covered is not undermined.

Specifically, we recommend CMS consider the following as it develops a Federal Implementation Plan and continues progress towards meeting the Strategy goals:

**Goal 1: Prevent New HIV Infections**

Ensuring that people living with and at risk for HIV are armed with the knowledge and tools to prevent transmission and acquisition of HIV is a cornerstone of the plan to end the HIV epidemic. Health insurance programs under the purview of CMS have an important role in increasing awareness of HIV and access to screening and prevention tools, including the full range of prescription drugs proven to protect against the transmission of HIV.

We urge CMS to update the Joint Informational Bulletin \textit{Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries}, last issued in 2016. Significant changes in federal guidance and HIV prevention biotechnology warrants updated recommendations to ensure appropriate access for all Medicaid and
CHIP enrollees. Updating and reissuing the bulletin will reaffirm to state Medicaid agencies that CMS is prioritizing the adoption of policies that will help bring an end to the HIV epidemic.

In addition to updating the 2016 Bulletin, we urge CMS to:

1.1 Increase awareness of HIV

- Ensure that pharmacists are reimbursed by public and private health insurance plans for HIV education and testing and in the promotion and provision of pre-exposure prophylaxis (PrEP).

1.2 Increase knowledge of HIV status

- Ensure at-home and same-day HIV testing is covered across all insurance types and that testing is available to everyone regardless of insurance- or provider-perceived “risk”. Testing people based on a provider-perceived “risk” does not always yield an accurate assessment of whether a patient would benefit from testing.
- Provide guidance to health departments that balance partner services with potential misuse of state HIV criminalization laws.
- Encourage Medicaid and private insurance plans to incorporate pharmacists who can educate consumers and prescribe PrEP, particularly those who serve as key health care providers for underserved communities.
- Work to end disparities in HIV prevention by encouraging all state Medicaid programs to cover routine HIV screening for their traditional Medicaid population – currently the only group that does not have mandatory access to routine HIV screening. This is particularly important in states that have not yet expanded Medicaid, many of which bear a disproportionate burden of the HIV epidemic.
- Analyze existing programmatic data to determine baselines and develop analyses of HIV testing services and patterns for future comparisons to measure and assess progress.
- Study and report on HIV testing data collected in the Physician Quality Reporting System.
- Educate Congress on the public health necessity of ending the congressional ban on federal funding for syringe exchange.
- Encourage all health insurance programs to include routine HIV screening in substance abuse treatment services.

1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options

The USPSTF Grade A recommendation for PrEP is an important and powerful development that should eliminate cost barriers to PrEP, including ancillary services required to get and maintain a PrEP prescription for people with health insurance. But CMS must ensure that all insurance plans subject to the requirement are in compliance and encourage states to eliminate barriers to PrEP in traditional Medicaid programs. CMS should also eliminate cost-barriers to PrEP for people in Medicare. Specific steps we recommend include:

- Enforce compliance with Section 2713 of the Affordable Care Act. Despite the United States Preventive Services Task Force giving PrEP an “A” grade (thus requiring most health plans to cover PrEP and ancillary services at no additional cost), many enrollees in private insurance plans still face inappropriate charges for PrEP and ancillary services.
• Conduct regular reviews of Qualified Health Plan formularies to identify where PrEP is listed as requiring cost sharing. Provide grants to state regulators to conduct Marketplace-wide audits of compliance with the preventive services mandate.

• Require insurers to incorporate PrEP and ancillary services in no-cost preventive services lists. Set uniform language that insurers can insert in their formularies to inform consumers that certain medications used for PrEP have $0 copays.

• Establish a complaint portal (with transparent accountability measures) where people can report plans (including those sold on the Marketplace, off the Marketplace, and provided through a self-insured employer) that apply cost sharing to PrEP, PrEP-related services, and other no-cost preventive care.

• Require transparency in billing so providers better understand how to submit claims for the provision of no-cost preventive care.

• Update the 2016 guidance to state Medicaid programs on access to HIV prevention services. Since the last HIV Bulletin to state Medicaid programs was published in 2016, there have been significant changes in federal guidance and HIV prevention biotechnology, warranting updated recommendations to states to ensure appropriate access for all Medicaid enrollees. Specifically, updated guidance should address, among other issues, coverage requirements for Descovy and Apretude and clarifications of federal requirements related to the coverage of PrEP and ancillary services without cost sharing.

• Communicate recently updated CDC guidelines to prescribers and encourage the adoption of universal PrEP access (“Providers should offer PrEP to anyone who asks for it”).

• Communicate U=U messaging to issuers and providers to convey that HIV treatment is prevention and should not be subject to administrative delays or bureaucratic barriers.

1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

• Promote HIV-related communications with primary care providers, including pharmacists, and incentivize incorporating HIV care into routine medical care.

• Ensure providers and pharmacists can be reimbursed for actual time spent with patients, to prioritize quality patient care over efficiency, and for improved HIV health outcomes.

• Incorporate PrEP and HIV testing in messaging across primary care, general wellness, and reproductive health care. PrEP and PEP are not adequately included in CMS' communication around reproductive health for cis-gender women, including in well woman exams.

• Ensure that students in health care education and training programs can enter the HIV workforce, including by implementing loan forgiveness program incentives, strengthening recruitment partnerships with Historically Black Colleges and Universities (HBCUs) and Hispanic-Serving Institutions (HSIs), and providing opportunities for professional and network development.

• Support advancement of the HIV Epidemic Loan-Repayment Program (HELP) Act (H.R. 2295) and the BIO Preparedness Workforce Act (H.R. 5602/S. 3244) to improve size and diversity of the HIV and infectious disease workforce.

• Approve Section 1115 waivers and State Plan Amendments that allow for community health workers to be reimbursed by state Medicaid programs for their services. Community health workers have been effective at promoting HIV prevention and linkage to care, and serve as “a bridge between the client, the community where the client lives and medical clinics or community-based organizations”.

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9 See, e.g., American Academy of HIV Medicine | ACRE Minority Student Open (aahivm.org).

10 Boston University School of Social Work, Center for Innovation in Social Work & Health, The Community Health Worker Role on the HIV Care Continuum.
Goal 2: Improve HIV-Related Health Outcomes of People with HIV

2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment

- Prohibit application of utilization management techniques by insurers that delay initiation of HIV treatment for a newly diagnosed patient.
- Investigate specialty pharmacy programs that introduce barriers to necessary prescription medication, including combination HIV drugs that can lower pill burden and approve adherence to prescribed regimens. In a recent Supreme Court case, CVS v. Doe, several HIV advocacy organizations submitted an amicus brief that highlighted the ways in which specialty pharmacy programs (particularly those that employ mail order requirements) can inherently delay access to prescription drugs.
- Ensure all Qualified Health Plans provide low- or no-barrier access to guideline HIV regimens. Historical analyses have shown that some insurers offer products on the Marketplace that place all or most component drugs used in guideline HIV treatment recommendations on high-cost formulary tiers (if covered at all). Proposed regulations indicate that such plan designs will be consider presumptively discriminatory. We encourage the Center for Consumer Information and Insurance Oversight (CCIIO) and the Office for Civil Rights (OCR) to prioritize enforcement against this form of discrimination, as plans certified for the 2022 plan year have still employed this discriminatory tactic.
- Ensure that insurance plans subject to the CMS oversight provide unimpeded coverage for all of the HIV medications included in the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.
- Require insurance coverage to adequately reimburse pharmacists and other providers’ involvement with linkage to care and time counseling a patient, and ensure that all associated services (e.g., labs, medications, visits) are covered.

2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

- Ensure the adequacy of patient privacy with regard to surveillance, particularly in states with HIV criminalization laws.
- Encourage all Medicaid programs to cover routine HIV screening, including in emergency room settings.
- Provide updated guidance to state Medicaid programs on access to HIV treatment services, including coverage of injectable Cabenuva, updated access to care recommendations regarding rapid ART, and guidance on access to care for people seeking gender affirming care and hepatitis C treatment.

2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs

- Improve care transitions and access to care for people in carceral settings. Approve Section 1115 waivers that extend access to Medicaid coverage for people in prisons or jails for the duration of their incarceration or for a period of time prior to their release. This improved continuity of care is critically important to address the disproportionate impact of the HIV epidemic on people who encounter the

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12 For example, UnitedHealthcare’s Tennessee 2022 Marketplace plans only covers two combination drugs used in guideline regimens recommended for people living with HIV who are treatment-naïve (Biktarvy and Truvada) and both are covered at 40% coinsurance (nearly $1000+ and $400+ a month) after the deductible is met.
13 See Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents online at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf.
criminal justice system and the persistent linkage to care issues experienced by people recently released from prison or jail.

- Improve transitions between Medicaid and Marketplace coverage to ensure continuity of care.
- Require all health insurance companies and coverage providers to publicly report viral suppression rates.

2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

- Improve HIV-related communications with primary care providers, including pharmacists, to incentivize incorporating HIV care into routine medical care.
- Ensure that students in health care programs can enter the HIV workforce, including by implementing loan forgiveness program incentives and strengthening recruitment partnerships with Historically Black Colleges and Universities (HBCU) and Hispanic-Serving Institutions (HSIs).
- Support advancement of the HIV Epidemic Loan-Repayment Program (HELP) Act (H.R. 2295) and the BIO Preparedness Workforce Act (H.R. 5602/S. 3244) to improve size and diversity of the HIV and infectious disease workforce.

2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

- Continue to protect the six categories and classes of clinical concern in Medicare Part D. These “protected classes,” which include antiretrovirals, secure vital access to care for older people living with HIV.
- Coordinate across the federal government to ensure long-term care facilities, assisted living facilities, and nursing homes are equipped to adequately care for people living with HIV who are aging.
- Ensure that CMS facilitates better coverage of provider time-spent-with-patient, particularly regarding drug-drug interactions and wellness assessments.

Goal 3: Reduce HIV-Related Disparities and Health Inequities

Despite progress towards ending the HIV epidemic, stark racial and ethnic disparities in access to care and health outcomes persist among those at risk for and living with HIV. We urge you to incorporate efforts to end the HIV epidemic as a priority in the Administration’s efforts to address racial and ethnic health disparities. Within efforts to end the HIV epidemic, specific focus should be given to policies that will increase access to screening, prevention, and treatment in communities experiencing the greatest impact of HIV.

3.1 Reduce HIV-related stigma and discrimination

- Ensure implementation of non-discrimination protections, including in health insurance where many people have trouble accessing treatment for chronic conditions and gender-affirming care due to discriminatory plan designs. Over the last several years, the federal government has ceded oversight responsibility for various certification activities, including “active certification reviews for prescription drug formulary and cost sharing outliers for states that perform plan management functions.”\textsuperscript{14} CCIIO and OCR should work with state regulators to delineate clear, public lines of responsibilities and identify where deference to states over monitoring and enforcement should be rescinded.

\textsuperscript{14} Ctrs. for Medicare and Medicaid Servs., Ctr. for Consumer Info. and Ins. Oversight, Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later, \url{https://perma.cc/3UMS-2FER}; Ctrs. for Medicare and Medicaid Servs., Ctr. for Consumer Info. and Ins. Oversight, Initial Guidance to States on Exchanges, \url{https://perma.cc/K85Y-5WKS}; Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375, 31,440 (May 18th, 2016) (“OCR is responsible for enforcement with respect to benefit design issues under Section 1557. States have an important role in ensuring compliance with nondiscrimination requirements respecting insurance, including benefit design, under CMS regulations and applicable State laws”).

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• Enforce antidiscrimination law by building partnerships with stakeholders and continuing outreach programs that facilitate compliance in prophylactic and cost-effective ways. Federal agencies (e.g., CCIIO, OCR, OSHA) should develop more partnerships with state entities and other federal offices to create best practices germane to health and anti-discrimination, and give direction to entities that must comply with non-discrimination protections.

• Proactively enforce Section 1557 of the Affordable Care Act and protect people living with HIV who experience discrimination in health programs and activities that accept federal financial assistance. Enforcement should particularly focus on intersectionality of protected bases. Many people living with HIV have multiple marginalized identities and a narrow understanding of nondiscrimination law could require that they artificially split their identities (e.g., Black, disabled, immigrant) to fit within different statutes’ enforcement mechanisms.

• Ensure that providers and patients are resourced in understanding discrimination and criminalization so they can get adequate assistance from legal and advocacy groups.

• Reform discriminatory policies on blood and organ donation, related to HIV status and PrEP usage.

3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

• Invest in initiatives informed and led by communities who experience disparities in new HIV infections, knowledge of status, and along the HIV care continuum.

• Structure all funding opportunities to require grantees to address racial and gender disparities in the HIV epidemic.

3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

• Ensure people living with HIV and from disproportionately impacted communities are meaningfully involved on agency advisory councils, including designated representation on the President's Advisory Council on HIV/AIDS (PACHA), the CDC/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHAC), and the Office of AIDS Research Advisory Council (OARAC).

3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities

• Issue an updated State Medicaid Director Letter highlighting opportunities for care coordination benefits that include housing, behavioral health, preventive services, and other critical linkage to care services for people living with HIV.\(^{15}\)

• Encourage states to use home and community-based services authority to implement food and nutrition interventions, such as medically-tailored meals, produce prescriptions, and medically-tailored groceries.

• Ensure that policies addressing social and structural determinants of health and co-occurring conditions can withstand budgetary and political flux.

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3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations

- Ensure that students in health care programs can enter the HIV workforce, including by implementing loan forgiveness program incentives, strengthening recruitment partnerships with Historically Black Colleges and Universities (HBCU) and Hispanic-Serving Institutions (HSIs), and providing opportunities for professional and network development.
- Support advancement of the HIV Epidemic Loan-Repayment Program (HELP) Act (H.R. 2295) and the BIO Preparedness Workforce Act (H.R. 5602/S. 3244) to improve size and diversity of the HIV and infectious disease workforce.

Goal 4: Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners and Interested Parties

4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence

- Require all health insurance companies and coverage providers to publicly report clinical quality indicators for HIV, sexually transmitted infections, and viral hepatitis.
- Incorporate tuberculosis in Goal 4.1, and support local, state, and national tuberculosis elimination efforts. People living with HIV are more likely to have a latent infection develop into tuberculosis, yet decreased funding of public health infrastructure has limited the ability for existing programs to monitor, prevent, and treat tuberculosis infections.
- Promote reform of state laws that classify fentanyl test strips as drug paraphernalia. Fentanyl test strips allow people to detect when drugs have been mixed or cut with fentanyl and prevent fentanyl-related overdose and overdose deaths.
- Ensure provider awareness of the efficacy of incorporating buprenorphine into HIV care settings.
- Correct misunderstandings about who can deliver buprenorphine. Recent changes in buprenorphine practice guidelines allow for an alternative notification of intent pathway for eligible providers seeking to treat up to 30 patients. Providers may forego previously-required federal certification requirements related to training, counseling, and other ancillary services.
- Address barriers to accessing hepatitis C treatment for the estimated 21% of people living with HIV who also have hepatitis C by eliminating non-evidence-based restrictions, which can include imposing stricter requirements for people living with HIV, requiring advanced liver disease, limiting coverage to certain specialists, and requiring abstinence from alcohol and substance use.16
- Work with federal agencies, including the CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA), to encourage innovative Medicaid payment and delivery models that include coverage of HIV prevention and care services and incorporation of a broad range of health care workers (e.g., reimbursement for peer navigators, community health workers, and other community-based providers) through application templates, letters to state Medicaid directors, and other sub-regulatory guidance, including:
  - Develop guidance urging states to meaningfully include HIV programs and defined goals in any Center for Medicare and Medication Innovation (CMMI) supported demonstration project or initiative.
  - Recruit HIV programs and experts to participate in the CMMI Health Care Payment Learning and Action Network.

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o Collaborate with HRSA to solicit ideas from Ryan White Program grantees on how statewide Medicaid health system transformation initiatives can engage and include HIV programs, providers, and services.

4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community

- Federal agencies, such as CCIIO, should work closely with state regulators in states that perform plan management functions, to ensure that Qualified Health Plans do not discriminate against people living with HIV through adverse tiering or inadequate provider networks.

4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy’s goals

- Communicate with the Office of National AIDS Policy (ONAP) to ensure the agency’s National HIV/AIDS Strategy efforts are adequately funded and staffed, and publicly reported upon. The agency should have a clear channel for continuous engagement and feedback by people living with or at risk of HIV and their allies.

CMS has many opportunities to improve access to healthcare, reduce health disparities, and support the end of the HIV epidemic through updated policies and regulation. We appreciate the opportunity to provide input on the National HIV/AIDS Strategy Federal Implementation Plan. We look forward to engaging with the federal government in its response to the HIV epidemic. Please contact us if we can be of assistance.

Respectfully Submitted,

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