FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

July 28, 2021

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–9906–P
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule (RIN 0938–AU60)

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. We are writing in response to the Proposed Rule titled "Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule" (RIN 0938–AU60).

We are supportive of many of the provisions proposed in this rule. Efforts to End the HIV Epidemic rely on the accessibility of high-quality, affordable health care insurance that is culturally-competent and covers the treatment and services people need to get and stay healthy. Access to HIV care and treatment ensures that people living with HIV achieve and maintain viral suppression, which prevents further transmission of HIV because individuals who are virally suppressed have effectively no risk of transmitting HIV to others.[1] In order to ensure that people living with HIV and other chronic conditions have meaningful access to care, we urge the Department of Health and Human Services (HHS) and the Department of Treasury to consider the following recommendations and concerns detailed below.

[1] *See, e.g.*, Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV, NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2018), https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf.

Navigator Program Standards

HHCAWG supports the proposed amendment that reinstitutes previous requirements that Navigators in federally-facilitated exchanges be required to provide consumers with information and assistance on certain post-enrollment topics, such as the Exchange eligibility appeals process, the Exchange-related components of the premium tax credit reconciliation process, and the basic concepts and rights of health coverage and how to use it. Millions of individuals find the process of applying for and using health insurance overwhelming, and many are not literate in health insurance terminology or processes.[2] Navigators, especially those who serve as trusted sources of information to underserved communities such as people living with or at risk of HIV, can help reduce health disparities by improving health literacy and assisting individuals in exercising their health care rights. Given the important role that Navigators can play in an individual's access to health care, it is vital that they be required to not only help consumers enroll, but also be available when consumers attempt to use their insurance post-enrollment.

HHCAWG further urges the Department of Health to restore requirements to have at least two in-person Navigator organization in each state and to ensure at least one of the organizations is a trusted community non-profit organization. Community entities with a physical presence will better know their communities and are better able to serve them because they interact with the target populations on an ongoing basis and are able to build relationships that transcend the application process. In-person assistance is especially critical in rural and underserved communities where people may not have reliable access to a computer or telephone, and may have increased hesitance to work with unfamiliar organizations. Thus, we strongly suggest the reinstatement of requirements to have at least two in-person Navigators in every state and ensuring at least one is a consumer-facing non-profit organization.

Exchange Direct Enrollment

HHCAWG supports the proposal to remove 45 C.F.R. § 155.221(j) and repeal the exchange direct enrollment option for state exchanges, state-based exchanges on the federal platform, and federally-facilitated exchanges. Continuing to allow states to transition away from a single, centralized exchange could increase confusion among individuals about where and how to access high-quality, affordable health care plans. We believe it is vital that consumers can reliably expect and gather unbiased information about their health care options from a single source – particularly given the various ways private brokers and insurers have been known to give inconsistent, inaccurate descriptions of plan options or steer consumers to specific plans that may not present the best value to the individual.[3]

---

[2] Karen Pollitz, et al., Consumer Assistance in Health Insurance: Evidence of Impact and Unmet Need, KAISER FAMILY FOUNDATION (Aug. 7, 2020), https://www.kff.org/report-section/consumer-assistance-in-health-insurance-evidence-of-impact-and-unmet-need-issue-brief/.

[3] Tara Straw, "Direct Enrollment" in Marketplace Coverage Lacks Protections for Consumers, Exposes Them to Harm, CTR. ON BUDGET & POLICY PRIORITIES (Mar. 15, 2019),

Open Enrollment

HHCAWG supports the proposal to lengthen the annual open enrollment period for the 2022 coverage year and beyond, in all Exchanges to November 1 through January 15, as compared to the current annual open enrollment period of November 1 through December 15. We would also support a longer open enrollment period, because as seen in many states' experiences, longer open enrollment periods have allowed more consumers to enroll in plans and reduce the number of uninsured and underinsured individuals and families.

Similarly, HHCAWG supports the proposal to establish a monthly special enrollment period for qualified applicants who are eligible for advanced premium tax credits and whose household income does not exceed 150% of the federal poverty level. By removing the barrier of limited enrollment periods, more people can become insured upon learning that purchasing a plan through the Marketplace will result in little to no extra monthly cost due to advanced premium tax credits. Easing such barriers to special enrollment periods has been an important strategy in the United States response to the COVID-19 pandemic, with over 1.5 million people enrolling in coverage during the COVID-19 special enrollment period. These special enrollment periods also allow the opportunity for younger and healthier enrollees to join the risk pool, resulting in more stable markets for insurers.

User Fees

HHCAWG supports the proposal to set the 2022 user fee rate at 2.75% of total monthly premiums charged by an insurer for each policy under plans offered through a federally-facilitated exchange, and 2.25% of the total monthly premiums for each policy under plans offered through a state-based exchanges on the federal platform. HHCAWG would also be in support of increasing such fees to 3.5% (the level in effect prior to 2020).

Marketplace user fees support critical exchange functions that directly support consumers interested in learning more about their health insurance options, including the operation and improvement of the HealthCare.gov website, the Marketplace call center, the Navigator program, consumer outreach, and advertising. Many of these budgets have been drastically insufficient in past years and thus current activities are inadequate. The Administration should restore outreach and enrollment assistance programs budgets and fund continued improvements to the underlying technology of HealthCare.gov and to the federally-facilitated marketplace's customer service.

Billing Regulations for Coverage of Abortion Services

HHCAWG strongly supports the proposed repeal of regulations which require Qualified Health Plan issuers that offer coverage of abortion services (subject to Hyde Amendment funding

https://www.cbpp.org/research/health/direct-enrollmentin-marketplace-coverage-lacks-protections-for-consumers-expose.

limitations) to separately bill for this portion of the policy holder's premium and to instruct members to pay for the separate bill in a separate transaction. Such a requirement creates unduly and burdensome hurdles for issuers who want to cover abortion services. Additionally, where requirements are burdensome, issuers may not be able to absorb such costs and may stop offering coverage of abortion services or pass these costs onto enrollees. This requirement showed a clear disregard for individuals seeking abortion services (a common, safe, and legally protected form of medical care in the United States) and directly contravened any goal of expanding access to high-quality health care coverage.

Section 1332 Waivers

HHCAWG supports the proposed modifications to regulations regarding Section 1332 Waivers, including changes to many of the policies and interpretations of the guardrails recently codified. The Affordable Care Act's (ACA) guardrails for Section 1332 Waivers require the program modification to cover at least as many people, with coverage at least as comprehensive and affordable as would be if a waiver did not exist, without increasing the federal deficit. Many states have used Section 1332 waivers to lower costs and make coverage more affordable through innovative reinsurance programs. However, the relaxed guardrails permitted with recent regulatory changes left many people vulnerable to state "innovations" that could drastically alter the standard of plans offered to individuals and that could create a segmented market where healthier individuals would be drawn to cheaper, less comprehensive coverage and people with higher healthcare needs (such as people living with HIV, hepatitis C, or other chronic conditions) would stay in the ACA-compliant market. These enrollment patterns would not only bring fiscal harm to those who inadvertently enrolled in cheaper, less comprehensive coverage that does not meet their medical needs, but would likely cause adverse selection and steeper premium increases for people enrolled in ACA-compliant plans.

HHCAWG opposes the reduction in public notice requirements for Section 1332 waivers under certain emergent situations. Requirements for Section 1332 public notice and opportunity for meaningful public input are statutory and designed to ensure public input and transparency in state efforts to transform health delivery systems. These opportunities allow those who advocate for vulnerable and historically underrepresented and underserved communities to notify officials of the negative impact such waivers can have. We urge the Department of HHS and the Department of Treasury to withdraw this particular proposal.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act (MHPAEA) has been under-enforced since enactment. Non-quantitative treatment limitations (NQTLs) disproportionately affect access to mental health services where comparable limits are not applied to other medical services. HHS has new statutory authority to investigate such disparities and engage in comparative analysis to review NQTLs for lack of parity and enforcement. HHCAWG supports incorporating compliance with the MHPEA as part of the requirement for plans to cover mental health and behavioral

health services as one of the ten Essential Health Benefits categories and look forward to the Department playing a more active role in enforcing these protections.

Network Adequacy

We are pleased that CCIIO will be developing a new network adequacy review process following the decision in *City of Columbus, et al. v. Cochran,* No. 18–2364, 2021 WL 825973 (D. Md. Mar. 4, 2021), and in doing so will set up a new regulatory standard for Qualified Health Plan provider networks for 2023. Some health care insurers use provider network structure to discourage people with higher cost conditions like HIV from enrolling in their plans. Developing and enforcing strong provider network standards is important to the health of these people. When HIV is managed by experienced HIV providers, people have better outcomes and more cost-effective care. More than 50% of people living with HIV in care receive services from the Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program, and the care of many of the individuals enrolling in Qualified Health Plans is managed by providers at Ryan White-funded clinical sites.

In reviewing and revising the provider networks for 2023, we recommend:

- Strengthening requirements to contract with essential community providers by increasing it to a minimum of 50% of the essential community providers within each category and monitoring and enforcing compliance with the enhanced essential community provider requirements.
- Requiring coverage for out-of-network providers at in-network cost sharing standards if a qualified specialist or an essential community provider category is not available within network according to network adequacy standards.
- Ensuring transparency and easy access to up-to-date provider directories that clearly indicate essential community providers and other specialty providers including infectious diseases and HIV providers.
- Allowing specialists to serve as primary care providers for people with HIV and others with chronic conditions.
- Working with HRSA's HIV/AIDS Bureau to ensure Qualified Health Plans issuers are contracting with Ryan White Clinical Providers to promote continuity of care and access to high quality care for QHPs enrollees.

Additional Comments

We applaud the Departments of Labor, Health and Human Services, and the Treasury's recent publication of "FAQs About Affordable Care Act Implementation Part 47" that addresses questions regarding the coverage of preventive services as required by Section 2713 of the Public Health Service Act.[4] These services include those recommended by the United States Preventive

[4] FAQ About Affordable Care Act Implementation Part 47 (June 19, 2021), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf.

Services Task Force (USPSTF) (rated "A" or "B"), immunizations recommended by the Advisory Committee on Immunization Practices, preventive services specific to infants, children, and adolescents as recommended by the HRSA's Bright Futures Project, and additional preventive services specific to women as set forth by HRSA. The guidance also answers questions specific to the coverage of Pre-exposure Prophylaxis (PrEP) and associated baseline and monitoring services.[5] Of note, the guidance makes clear that the USPSTF's recommendation of PrEP encompasses not only the FDA-approved PrEP antiretroviral medications, but specific ancillary services as well. These include: HIV testing; Hepatitis B and C testing; Creatinine testing and calculated estimated creatine clearance (eCrCl) or glomerular filtration rate (eGFR); Pregnancy testing; Sexually transmitted infection (STI) screening and counseling; and Adherence counseling. Additionally, the guidance states that insurers subject to Section 2713 of the Public Health Service Act may not restrict the coverage of PrEP and associated services as specified in the USPSTF recommendation. The FAQ also confirms that when insurers apply restrictive medical management techniques in manners outside of the scope of the USPSTF recommendation, they "must have an easily accessible, transparent, and sufficiently expedient exceptions process (for example, one that allows prescribing and accessing PrEP medications on the same day that the [individual] receives a negative HIV test or decides to start taking PrEP) that is not unduly burdensome on the individual or provider."

For insured individuals, cost sharing associated with both the medication and the clinic and lab visits has been a persistent barrier to PrEP, making the public and private insurance coverage and cost-sharing requirements associated with the USPSTF Grade A rating for PrEP an important opportunity to expand access. The Administration's Ending the HIV Epidemic initiative, which aims to reduce new HIV infections by 90 percent by 2030, includes increasing PrEP utilization as a core pillar of the initiative.[6] We therefore urge HHS to ensure that Qualified Health Plans sold on the Marketplace for Plan Year 2022 are in full compliance with this mandated coverage by requiring certification of compliance from Qualified Health Plan issuers, conducting compliance checks with plan claims data, and collecting PrEP-related policy information from issuers participating in the Marketplace.

As the Departments consider proposed changes for the Notice of Benefits and Payment Parameters for Plan Year 2023, we urge the consideration of ongoing issues that people living with HIV face with plans sold on the Marketplace. Specifically, we recommend:

- *More restrictive mid-year formulary changes must be prohibited*: There are countless examples of consumers with an HIV or chronic condition diagnosis who choose a plan based on the formulary design and coverage, only to have their issuer make a more restrictive mid-year change to the formulary that excludes a needed medication or places

[5] PrEP when taken regularly can prevent a person from getting HIV from sex or injection drug use The USPSTF graded PrEP with an "A" recommendation in June 2019. *See* Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement, 321 JAMA 2203 (June 2019), https://jamanetwork.com/journals/jama/fullarticle/2735509#full-text-tab.

[6] HIV.gov, Ending the HIV Epidemic: A Plan for America, available at https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

the medication on a higher cost-sharing tier. We urge CMS to amend 45 C.F.R. §147.106 to include a new subsection explicitly prohibiting *adverse* mid-year formulary changes.

- *Prescription drug non-discrimination standards must be strengthened*: More specificity is needed in non-discrimination provisions, such as those found in 45 C.F.R. §156.122, including explicit prohibitions on plan designs that are likely to dissuade enrollment from individuals living with chronic conditions and disabilities. Specifically, CMS should identify that plan designs that place all or most of the component drugs used in guideline regimens for a chronic condition on the most expensive formulary tiers discourage enrollment from people living with those conditions and are prohibited.

- *Co-pay accumulators must be prohibited*: Co-pay accumulators (the practice of a plan or pharmacy benefit manager refusing to count payments made with manufacturer co-pay cards toward a beneficiary's deductible or out-of-pocket maximum) continue to place disproportionate cost burdens on individuals with chronic conditions. The practice essentially moots the ACA's cost-sharing protections for individuals that use these co-pay cards and does nothing to save costs when applied to consumers with no other choices. CMS should limit accumulators only to situations where a generic equivalent is available.

- *Standardized plan options should make prescription drug coverage more accessible:* HHCAWG is encouraged that CMS intends to propose specific standardized plan designs in the 2023 Notice of Benefits and Payment Parameters. Affordability continues to be a major challenge for people living with HIV and other chronic conditions due to high deductibles and prescription drug cost-sharing requirements. For example, when a plan requires co-insurance in its coverage of prescription drugs, individuals face unpredictable out-of-pocket costs and may be required to pay a large amount of their health care costs upfront, instead of spreading out costs more evenly over the plan year. Standardized plan options should eliminate coinsurance and ensure that coverage of prescription drugs are not subject to a deductible.

- *Special Enrollment Period Verification must be eliminated:* The 2017 Market Stabilization Rule imposed burdensome verification requirements for enrollees using certain special enrollment periods to enroll in or make changes to their coverage. This change was made despite overwhelming evidence that burdensome documentation requirements are a barrier to accessing coverage and a lack of evidence of widespread abuse of special enrollment periods by ineligible consumers. We urge HHS to reconsider its procedures for *all* special enrollment periods and reinstate application and verification standards in place prior to the 2017 Market Stabilization Rule.

- *Special Enrollment Period metal level restrictions must be eliminated:* The 2017 Market Stabilization Rule also finalized changes to regulations that harm consumers by prohibiting them from changing metal levels mid-year when they experience a qualifying

life event that triggers a special enrollment period. This regulation runs afoul of the ACA's guaranteed availability requirement, which requires insurers to accept any individual who applies for coverage and does not permit restrictions on plan choice. Metal level restrictions reduce consumer choice and can prevent individuals and families from enrolling in plans that are affordable and provide appropriate coverage. While we appreciate that the finalized 2021 and 2022 notices of benefits and payment parameters remove some or all metal level restrictions for consumers who lose cost sharing reductions or tax credit eligibility, these changes do not go far enough. Instead, HHS should entirely eliminate metal level restrictions for all special enrollment periods.

- *Special Enrollment Period continuous coverage requirements must be eliminated:* The 2017 Market Stabilization Rule finalized changes to regulations that impose continuous coverage requirements as a pre-condition for certain special enrollment periods (such as for marriage or permanent moves). This also runs afoul of the ACA's guaranteed availability requirement, which requires insurers to accept any individual who applies for coverage and does not include exceptions for consumers who were uninsured for more than 60 days prior to an event triggering the special enrollment period. Life circumstances can inevitably result in gaps of coverage, particularly for lower-income individuals who may not have been financially able to afford a health care plan before their marriage or move. We urge HHS to reconsider and remove continuous coverage requirements for these special enrollment periods.

- *Coverage lockouts due to non-payment of premiums must be prohibited:* The 2017 Market Stabilization Rule finalized a new interpretation of the ACA's guaranteed availability requirement, permitting insurers to deny future enrollment in coverage if a consumer has previously lost coverage due to non-payment of premiums. The statutory guaranteed availability requirement does not include any exceptions for consumers who have previously lost coverage due to non-payment of premiums though. Furthermore, the 2017 interpretation is not necessary. An overwhelming majority of consumers who miss premium payments catch up on past-due payments or voluntarily terminate coverage, and other existing laws and policies reduce incentives for "gaming" grace periods. The practice of denying future enrollment is particularly harmful in the 54% of counties where only one or two issuers participate in the Marketplace.[7] Additionally, loss of coverage can sometimes result from technical or accounting irregularities that are out of a member's control and are difficult or impossible for the consumer to prove during an appeal. We encourage HHS to rescind the reinterpretation of the guaranteed availability requirement and instead solicit public comment on other measures that allow issuers to recoup unpaid premiums while still maintaining beneficiary enrollment.

[7] Daniel McDermott & Cynthia Cox, Insurer Participation on the ACA Marketplaces, 2014-2021, KAISER FAMILY FOUNDATION (Nov. 23, 2020), https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/.

Thank you for the opportunity to provide feedback and for your thoughtful consideration of these comments. If you have further questions, please reach out to HHCAWG co-chair Phil Waters at pwaters@law.harvard.edu with the Center for Health Law and Policy Innovation, Rachel Klein at rklein@taimail.org with The AIDS Institute, and Aisha Davis at adavis@aidschigaco.org with AIDS Foundation of Chicago.

Respectfully submitted by:

AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Healthcare Foundation (AHF)
AIDS Foundation Chicago
American Academy of HIV Medicine
APLA Health
Center for Health Law and Policy Innovation
Community Access National Network - CANN
Community Research Initiative, Inc. (CRI)
HealthHIV
HIV+Hepatitis Policy Institute
HIV Dental Alliance
HIV Medicine Association
iHealth
International Association of Providers of AIDS Care
National Alliance of State & Territorial AIDS Directors (NASTAD)
Positive Women's Network-USA
Prevention Access Campaign
San Francisco AIDS Foundation
The AIDS Institute
Vivent Health