FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

January 31, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information on Essential Health Benefits

Dear Secretary Becerra:

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-related healthcare and support services. Our organizations serve and work on behalf of people with serious, complex chronic illness who rely heavily on the patient protections in the Affordable Care Act (ACA) to ensure that they have access to the services and treatments needed to prevent disease, cure illness and manage chronic health conditions.

Thank you for the opportunity to provide comments to inform future rulemaking on the essential health benefits (EHB) requirement of the ACA. We greatly appreciate your ongoing efforts to ensure the effective implementation of the patient protections and consumer-focused policies of the ACA, of which the EHB are a critical part.

The ACA's standards obligating insurers to cover all essential health benefits are of fundamental importance to the people we represent. We thank the Department for its commitment to ensuring access to comprehensive coverage and preventing discrimination in benefit design. We also urge the Department continue to use its broad authority under the ACA to update and strengthen EHB standards to ensure plans cover all the benefits and services patients need, and we ask that you consider the following comments in response to the questions raised in the Request for Information (RFI).

Benefit Descriptions in EHB-benchmark Plan Documents

As an initial matter, HHCAWG expresses its concern that HHS's approach to defining EHB by reference to benchmark plans abdicates the Secretary's responsibility under the Affordable Care Act (ACA) to define EHB[1] and creates variation in terms of the benefits to which individuals are entitled based on where they live. Moreover, because the benchmark plans were themselves based on pre-ACA coverage, the benchmark approach to defining EHB risks perpetuating discriminatory plan designs and longstanding

[1] Affordable Care Act § 1302(b).

health disparities.[2] This issue is of particular concern to HHCAWG, given that Black and Latino people and sexual minorities are disproportionately impacted by HIV, yet effective prevention and treatment do not adequately reach these communities.[3]

To the extent that CMS maintains the benchmark plan approach to defining EHB, HHCAWG concurs with CMS' assessment that states' EHB benchmark plan documents can describe benefits differently and without clear and complete information on the benefits covered in each of the 10 categories. We therefore support CMS requiring more specificity and less ambiguity in EHB benchmark plan documents. However, we would strongly oppose any effort to make greater standardization a prerequisite for CMS fulfilling its obligation to periodically review and update the EHB. While the current state of benchmark plan documents may, in fact, make it more difficult to reliably compare state benchmark plans, that cannot stand in the way of CMS beginning the urgent and statutorily required work of considering needed updates to the EHB.

We note with some concern CMS' conclusion that benchmark ambiguity has not resulted in consumer harm nor in exclusion of services that are generally understood to be covered.[4] Many consumers still find health insurance confusing and may not know whether their plans are covering all of the benefits they should. Moreover, few consumers are aware of how to report a complaint to their state department of insurance, and fewer still take the steps to do so. We also note that CMS has no independent system for collecting and monitoring these types of consumer complaints and the outcomes (aside from its enforcement role with respect to health insurance issuers in certain limited states).

Rather than conclude enforcement is sufficient and exclusions don't occur, we ask the Department to strengthen its enforcement of existing EHB standards and increase resources dedicated to such enforcement. This includes timely oversight in the states in which the Department directly enforces ACA protections as well as increased support for the states that are serving as primary regulators *and for residents of all states* who, understandably, may not know where to go to get help for a problem with their coverage that is meant to be ACA-compliant. There should be better information for consumers to know who to contact when they have a complaint, and, if they initially seek help in the wrong place, their complaint should be seamlessly routed to the appropriate enforcement agency.

HHCAWG is particularly concerned that certain EHB standards of great importance to the HIV community are not sufficiently clear and are inadequately enforced. For example, for transgender women living with HIV, research has linked better HIV care outcomes to receipt of prescription estrogen,

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[2] *See* The Commonwealth Fund, How Insurers Can Advance Equity Under the Affordable Care Act (August 10, 2021), https://www.commonwealthfund.org/blog/2021/how-insurers-can-advance-health-equity-under-affordable-care-act.

[3] HIV.gov, Impact on Racial and Ethnic Minorities (January 26, 2022), https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities.

[4] 87 Fed. Reg. 74,098 (Dec. 2, 2022).

a form of gender-affirming care.[5] Although plans that must offer EHBs are subject to standards that prohibit discrimination based on health condition, such as gender dysphoria,[6] many of the benchmark plans and benchmark plan options available to states include plans that have explicit and/or potentially discriminatory exclusions in them.[7] HHS is aware of these exclusions, since the regulations require them to be submitted to HHS for review.[8] We are also aware of substance use restrictions on hepatitis C treatment being imposed in private plans,[9] and such restrictions in Medicaid programs remain common, including in Medicaid expansion states.[10] These restrictions improperly discriminate against people with substance use disorder. We therefore urge CMS to clarify and strengthen its enforcement of EHB standards (including 45 CFR § 156.111(b)(2)(v)) and § 156.125) when the benchmark plan or benchmark plan options available to a state contain discriminatory exclusions.

Moreover, as discussed further below, discriminatory benefit design in violation of 45 CFR § 156.125(a) remains a critical issue for people living with HIV and others with chronic conditions. While we welcomed the additional language in the 2023 Notice of Benefit and Payment Parameters clarifying this rule, including that discriminatory benefit designs "must be cured regardless of how [they] originated,"[11] we remain concerned about the ongoing lack of enforcement of these rules and the delegation of enforcement responsibility to the states, which has thus far proved insufficient. We urge CMS to take a more active role in enforcing the EHB anti-discrimination regulations, including in its review of EHB benchmark plan documents.

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[5] *See* Jules Chyten-Brennan et al., *Brief Report: Role of Gender-Affirming Hormonal Care in HIV Care Continuum Outcomes When Comparing Transgender Women with Cisgender Sexual Minority Men*, 91 J. Acquired Immune Deficiency Syndromes 255 (Nov. 1, 2022), DOI: 10.1097/QAI.0000000000003056.

[6] *See* 45 C.F.R. § 156.125(a).

[7] *See e.g.*, Kentucky (excluding coverage of "[s]ex transformation operations and related services"), Louisiana (excluding coverage of "treatment related to sex transformation, sexual function, sexual dysfunctions or inadequacies"), and Oklahoma (excluding coverage of "[f]or transsexual [s]urgery or any treatment leading to or in connection with transsexual [s]urgery"). Benchmark plan information was obtained from https://www.cms.gov/cciio/resources/data-resources/ehb. *See also*, *Kadel v. Folwell* 446 F.Supp.3d 1, 18 (M.D.N.C. 2020) (discussing state plan exclusion that barred "treatment in conjunction with proposed gender transformation" and "sex changes or modifications"). In *Kadel*, the state defendants "attempt[ed] to frame the exclusion as one focused on 'medical diagnoses, not . . . gender," but the district court rejected this argument, noting that "the diagnosis at issue—gender dysphoria—only results from a discrepancy between assigned sex and gender identity." *Id.*

[8] 45 CFR § 156.120(b)(2)(iv).

[9] *See* BlueCross BlueShield of Arizona, Pharmacy Coverage Guidelines for Direct Acting Antiviral Agents for Hepatitis C Virus (HCV), https://www.azblue.com/~/media/azblue/files/pharmacy-forms-mastery-directory/standardpharmacyplans/pharmacy-coverage-guidelines-and-precertification-forms/epclusa-and-sofosbuvir-velpatasvir.pdf (including among criteria for therapy that there be "no alcohol and/or no substance use in the past 6 months").

[10] *See* Hepatitis C: State of Medicaid Access, *https://stateofhepc.org/report/* (tracking states that impose substance use restrictions on hepatitis C treatment in Medicaid).

[11] 87 Fed. Reg. 27,297 (May 6, 2022).

Typical Employer Plans

The EHB RFI notes that CMS is seeking comment on changes in the scope of benefits offered by employer plans since plan year 2014, because the ACA requires EHB to be at least as generous as the "typical employer plan."[12] Since 2014, the scope of coverage in large employer-sponsored health insurance plans has deteriorated as plans have shifted more costs to enrollees through increasing deductibles and higher cost-sharing, especially for people with more complex health care needs. As CMS undertakes its review of EHB, we caution against any revision of the definition of a "typical employer plan" that would result in any reduction in the scope of benefits required to meet an EHB benchmark. Rather, we urge CMS to strengthen the EHB regulations and guidance to ensure that plans are covering the full range of services needed to provide comprehensive access to care.

In recent years, employer plans have focused on reducing their share of costs for prescription drugs, developing creative policies that undermine out-of-pocket cost protections for enrollees and enable the plans to capture third-party financial assistance offered to enrollees from pharmaceutical manufacturers and charitable assistance funds. These arrangements are sometimes referred to as "copay accumulator adjustment policies" or "copay maximizer programs," because they increase the out-of-pocket burden on enrollees. To implement these programs, employer plans work with Pharmacy Benefit Managers (PBMs) to designated certain high-cost drugs as "non-EHB." In some cases, plans have carved all specialty medications out of their "EHB" prescription drug benefit. This enables the plan to bypass ACA protections limiting out-of-pocket costs for enrollees. Health plans have justified these attempts to evade ACA cost sharing protections by arguing that if a plan covers the minimum required drugs, additional covered drugs are not EHBs.[13] Issuers also cite to CMS guidance that states plans can "continue to impose annual and lifetime dollar limits on benefits that do not fall within the definition of EHB."[14] Some plans have taken the additional step of requiring enrollees to sign up for manufacturer assistance programs in order to get coverage for a given drug.

Since 2014, the prescription drug benefit has become even more essential for people living with chronic illness. Advances in scientific understanding and innovation have led to revolutionary new therapies that dramatically improve quality of life and alleviate complications from serious illness. While we recognize that new treatments are expensive, that is precisely the reason that people need health insurance and why the ACA was enacted: to ensure that individuals are not denied care they need just because it is expensive. Copay accumulator adjustment policies, copay maximizer programs, and other evolutions of

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[12] ACA § 1302(b)(2)(A) and 45 CFR § 156.110(a)

[13] *2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, EXPRESS SCRIPTS; Meghan Pasicznyk, *Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, EVERNORTH (Oct. 7, 2021), https://www.express-scripts.com/corporate/articles/reducing-specialty-drug-costs. Under 45 C.F.R. § 156.122(a), plans must cover the greater of one drug per U.S. Pharmacopeia class and category, or the state's benchmark. Note the ACA explicitly states that the regulation should not be construed as limiting a plan if it wants to provide additional benefits. 42 U.S.C. § 18022(b)(5).

[14] *Frequently Asked Questions on Essential Health Benefits Bulletin* 4, CTRS. MEDICARE & MEDICAID SERVS. (Dec. 16, 2011), https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf.

these policies undermine the ACA's patient protections. We welcome HHS's unequivocal affirmation that "plans [can] exceed the minimum number of drugs required to be covered and that additional drugs [will] still be considered EHB."[15] However, we urge HHS to take additional steps to protect access to this important category of EHB for people living with chronic and lifelong conditions.

We strongly urge HHS to establish robust coverage standards for prescription drugs and other EHB categories; and to rigorously enforce those standards amid increasing issuer attempts to evade their obligations to enrollees under the law.

Review of EHB

The ACA directs HHS to periodically review the EHB framework. Under the statute, this review must include a report to Congress and the public that contains, among other things, assessments of (1) whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost; and (2) whether EHB must be modified or updated to account for changes in medical evidence or scientific advancement. These provisions of the ACA also explicitly charge the Department with the task of updating benefit requirements to address any gaps in access to coverage or changes in the evidence base that are identified in these reviews. The state benchmark process currently relies on benefit designs that are more than five years old and there are numerous areas in which benefit standards need to be reassessed and likely updated. Further, in the absence of HHS fulfilling its statutory obligation to review and update the EHB, the task falls to states to update their benchmark plans to respond to changing coverage and public health needs, but doing so puts states at risk of incurring the costs of these updates.[16]

In order to conduct a thorough and regular review, HHS should establish a process that is evidence-based, transparent, operates with clearly articulated timeframes for reviewing and reporting, allows for public input, and includes consumer and patient representatives. Such a review would identify barriers to accessing services due to coverage and cost, changes in medical evidence and scientific advancement, and any gaps in coverage for needed services. Below we offer comments on specific areas raised in the RFI.

Barriers of Accessing Services Due to Coverage or Cost

Significant Barriers for Accessing Mental Health and Substance Use Disorder Services

Mental health and substance use disorders are more prevalent among people with HIV than the general population.[17] [18] People with HIV and HIV clinicians caring for people with HIV frequently report access to mental health and substance treatment as one of their biggest challenges. A Centers for Disease Control

[15] 87 Fed. Reg. 74100.
[16] See 45 CFR §155.170
[17] National Institutes of Health. HIV and AIDS and Mental Health. https://www.nimh.nih.gov/health/topics/hiv-aids
[18] Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Considerations for Antiretroviral Use in Special Patient Populations. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/substance-use-disorders-and-hiv

and Prevention study found that more than 20% of people with HIV have unmet mental health needs. Barriers include an acute lack of mental health and substance use treatment providers generally that is further complicated when looking for providers with expertise in HIV. In addition to provider shortages, stigma and a lack of expertise in issues affecting people with HIV can make it difficult for people with HIV to access mental health and substance use treatment.

It is therefore essential to ensure strong mental health and substance use treatment provider networks, which can be enhanced through telehealth as described below. In addition, it is important that mental health and substance use disorder benefits cover the continuum of services necessary for effective treatment options and that arbitrary limits on length of treatment, coverage restrictions and utilization management are not placed on mental health and substance use treatment services.

Strategies to Broaden Access to Telehealth Services

As evidenced by the COVID-19 Public Health Emergency, increased access to telehealth services can remedy barriers to care such as a lack of a provider with expertise in HIV, mental health and substance use treatment and lack of transportation and time constraints associated with traveling to in-person appointments, which have been linked to interruptions in HIV care.[19] [20] Some people seeking HIV prevention or treatment have also expressed a preference for telehealth appointments out of concern for privacy.[21] By reducing barriers to care such as transportation, time constraints, and exposure to stigma, telehealth makes care for HIV and any co-occurring conditions more easily accessible.

The HIV community has largely welcomed the increased availability of telehealth and urges CMS to adopt EHB regulations that continue to facilitate telehealth access as an option for people with HIV. In doing so, we urge CMS to put safeguards in place to ensure the use of telehealth does not worsen health inequities, such as by monitoring outcomes and issuing guidance that urges plans to facilitate access to technology, support technical literacy and ensure all tele-health applications are designed to engage individuals with limited English proficiency.[22] It also is critical that plans cover audio-only visits for individuals without phones or internet service that supports video visits.[23]

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[19] Centers for Disease Control and Prevention. Data Tables: Quality of Life and HIV Stigma— Indicators for the National HIV/AIDS Strategy, 2022–2025 CDC Medical Monitoring Project, 2017–2020 Data Cycles, https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-30.pdf

[20] Dima Dandachi et al., *Integration of Telehealth Services in the Healthcare System: with Emphasis on the Experience of Patients Living with HIV*, 67 Journal of Investigative Medicine 815 (2019), https://perma.cc/22SR-K7KJ.

[21] *Id.*

[22] Wood, BR, et al. Advancing Digital Health Equity: A Policy Paper of the Infectious Diseases Society of America and the HIV Medicine Association**.** *Clinical Infectious Diseases*, Volume 72, Issue 6, 15 March 2021, Pages 913–919, https://doi.org/10.1093/cid/ciaa1525.

[23] Armstrong, WS, et al. Innovations in Human Immunodeficiency Virus (HIV) Care Delivery During the Coronavirus Disease 2019 (COVID-19) Pandemic: Policies to Strengthen the Ending the Epidemic Initiative—A Policy Paper of the Infectious Diseases Society of America and the HIV Medicine Association. *Clinical Infectious Diseases*, Volume 72, Issue 1, 1 January 2021, Pages 9–14, https://doi.org/10.1093/cid/ciaa1532.

While we strongly support expanded telehealth access for those who prefer it, we also urge CMS not to permit telehealth access to take the place of requirements that ensure adequate access to in-person services for those who would be better served in that setting or who prefer in-person care. Building trust between patients and providers is important for effective, patient-centered HIV care, and some providers have reported more difficulty establishing a connection with their patients when providing telehealth services.[24] In one study involving older individuals living with HIV, participants reported various communication challenges in telehealth visits, including technological problems and the sense that telehealth visits were shorter and less open-ended.[25] These types of concerns are particularly important for people who are initiating HIV care, as early clinical experiences have been found to significantly impact retention in care.[26] Further, telehealth can be associated with unique privacy concerns, such as when patients have not disclosed their HIV status to household members and/or lack a private space in their living environment in which to meet with an HIV care provider.[27]

Impact of Strategies to Reduce Utilization and Costs on HIV Care

Prior authorization and other utilization management techniques can have serious consequences for patients when they result in delayed or denied care. Data for marketplace enrollees show that, on average, 17 percent of claims for in-network services were denied for reasons that include being found not medically necessary or for failure to obtain prior authorization or a referral.[28] In reviewing EHB, we urge the Department to ensure any utilization management is grounded in medical and scientific guidelines and is not used as a tool to restrict access to EHB. EHB's promise of providing access to a comprehensive set of benefits will be seriously undermined if insurers are able to use plan rules and care review programs to limit access to those services.

Prior authorization and other utilization management techniques delay or prevent access to HIV prevention and treatment services and increase administrative burden resulting in increased costs to the health care system.[29] A recent study found that Qualified Health Plans (QHP) in the South were 16 more times likely than other regions in the country to impose prior authorization requirements for HIV pre-exposure prophylaxis or PrEP.[30] We strongly recommend that CMS monitor the utilization management processes applied to HIV prevention and treatment drugs and urge plans to ensure streamlined access to drugs prescribed for HIV prevention and treatment according to the Department

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[24] Ofole Mgbako et al., *COVID-19, Telemedicine, and Patient Empowerment in HIV Care and Research*, 24 AIDS and Behavior 1990 (2020), https://perma.cc/L5AG-ZAN9.

[25] Abigail Baim-Lance et al., *supra* note 21.

[26] Dima Dandachi et al., *supra* note 13.

[27] *Id.*; Melissa Grove et al., *supra* note 24.

[28] Karen Pollitz and Matthew Rae, "Claims Denials and Appeals in ACA Marketplace Plans in 2020," KFF, Jul. 5, 2022.

[29] Raper JL, Willig JH, Lin HY, et al. Uncompensated medical provider costs associated with prior authorization for prescription medications in an HIV clinic. Clin Infect Dis 2010; 51:718–24..

[30] McManus, KA, et al. Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States. JAMA Netw Open. 2020 Jun 1;3(6):e207445. doi: 10.1001/jamanetworkopen.2020.7445.

of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV* and the *Clinical Practice Guideline on Preexposure Prophylaxis for the Prevention of HIV Infection in the United States*.

Cost and Coverage Barriers to Advances in HIV Prevention and Treatment

In January 2021, the first long-acting injectable for HIV treatment (cabotegravir, rilpivirine) was approved, followed by the approval of a long-acting injectable for HIV prevention in December 2021 (cabotegravir), and a long-acting injectable treatment for treatment experienced people with HIV without other options was approved in December 2022 (lenacapavir). These new options have the potential to revolutionize HIV prevention and treatment for some populations by preventing treatment disruptions, reducing pill burden and reducing the stigma associated with HIV prevention and treatment. The currently available long-acting prevention and treatment options require administration in a clinical setting by a health care professional complicating coverage and service delivery options.

Implementation of long-acting injectable therapies has been severely hampered by service delivery and health insurer coverage issues, including many plans covering long-acting injectables for HIV prevention and treatment under the medical benefit rather than the prescription drug benefit.[31] [32] Navigating the medical benefit processes places additional administrative and cost burden on providers, and also subjects some patients to facility fees as high as $300 per visit. One clinic in San Francisco documented the potential for long-acting treatment options to improve health outcomes and reduce health inequities for individuals who use drugs and/or experience homelessness when insurance barriers are reduced.[33] The clinic only serves individuals who are uninsured or with public insurance, which alleviated health insurance coverage issues and contributed to their early success. With the availability of novel delivery mechanisms for prevention and treatment service delivery, we urge CMS to consider as part of any minimum drug coverage requirement that coverage of novel mechanisms be required under the prescription drug benefit above the minimum requirement.

Are there ways in which the EHB definition needs to be modified to reflect changes in medical evidence and scientific advancement?

Coverage for Health-Related Social Needs

Current evidence supports coverage for health-related social needs, from the perspective of improving health outcomes and whole person care and lowering health care costs over the long-term. For people with HIV – ensuring their basic needs are met can be foundational to engaging in HIV care and treatment. It is now well documented that housing instability is a significant barrier to HIV services and

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[31] Thornhill, J, Orkin, C. Long-acting injectable HIV therapies: the next frontier Curr Opin Infect Dis. 2021 Feb 1;34(1):8-15. PMID: 33337617.

[32] Collins, LF, et al. Early Experience Implementing Long-Acting Injectable Cabotegravir/Rilpivirine for Human Immunodeficiency Virus-1 Treatment at a Ryan White-Funded Clinic in the US South. Open Forum Infect Dis. 2022 Sep 2;9(9):ofac455. PMID: 36147599.

[33] Christopoulos, KA. First Demonstration Project of Long-Acting Injectable Antiretroviral Therapy for Persons With and Without Detectable HIV Viremia in an Urban HIV Clinic. Clin Infect Dis 2022 Aug 1;ciac631.

affects outcomes in addition to quality of life for people with HIV.[34] According to the latest Ryan White Program client level data, the viral suppression rate for clients who were unstably housed was 77.3% compared to 90.8% for clients with stable housing.[35] Food insecurity also is associated with poor outcomes for people with HIV. [36] In addition to housing and nutritional support, other key supports important to engagement in care are transportation and childcare. Case management services also play a critical role to help ensure basic needs are met, avoid disruptions in benefits and to support coordination of care for co-occurring condition, including mental health and substance use disorder services.

We also noted that based on the experiences and reports from Ryan White Programs – the need for assistance with social needs related to health care has grown significantly since the beginning of the COVID-19 pandemic in 2020. To help advance health equity, we urge CMS to consider actions that will increase coverage of services to address social needs and reduce variability in scope of coverage and benefits across states to ensure people with HIV and others complex chronic conditions have access to the continuum of services that contribute to their health and quality of life.

Addressing Gaps in Coverage

We urge CMS not to rely on consumer complaints to measure the breadth of gaps in coverage. CMS' claims data for marketplace enrollees, for example, shows that an average of 16 percent of claims were denied in 2020 as an excluded service.[37] Yet marketplace enrollees appealed only 0.1 percent of denied claims – further evidence that consumers either don't know about their options for resolving problems with their health coverage, or don't have the resources to pursue them.[38]

We encourage CMS to look broadly at the issue of gaps in coverage. In addition to overt lack of coverage for given services, insurer practices such as utilization management (discussed above), lack of providers to deliver a service, or high cost-sharing that makes a service unaffordable can also create gaps in coverage for people with chronic conditions.

Network adequacy has long been a concern, especially for people in rural and underserved urban areas. Insufficient provider networks undermine EHB protections by putting care out of reach, even when it is covered. While expanded access to telehealth holds promise to address some of the disparity, CMS must

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[34] CDC. Issue Brief: The Role of Housing in Ending the HIV Epidemic. Online at: https://www.cdc.gov/hiv/policies/data/role-of-housing-in-ending-the-hiv-epidemic.html

[35] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021. ryanwhite.hrsa.gov/data/reports. Published December 2022.

[36] Mailman School of Public Health - Columbia University. Community Health Advisory Information Network. Fact Sheet. https://www.glwd.org/wp-content/uploads/2018/10/CHAIN-Factsheet1.pdf

[37] Karen Pollitz and Matthew Rae, "Claims Denials and Appeals in ACA Marketplace Plans in 2020," KFF, J. ul. 5, 2022.

[38] Ibid.

explore additional avenues to ensure that people in underserved communities have appropriate access to EHB services.

In addition, while chronic disease management is an explicit category of EHB, the lack of clarity and standards makes it difficult to determine whether patients are receiving the support they need. It is often unclear what types of services are being covered within this category and whether plans are covering them for a comprehensive range of chronic diseases. For example, as described above, although case management services for people living with HIV are covered by the Ryan White Program, case management is not commonly covered by private health plans and should be to appropriately manage the care for people living with HIV. We therefore urge the Department to set – and strongly enforce – standards for what must be covered for this category of EHB.

CMS seeks comment on whether EHB should be updated to require coverage of behavioral health crisis services. As stated above, mental health and substance use treatment are particularly important for people living with and at risk for HIV. We strongly urge CMS to require coverage of these services in EHB.

Preventive services provided at no cost to consumers are one of the most widely used and important benefits. Yet uneven enforcement and inadequate guidance limits access to some expert-recommended services and treatments. For example, The AIDS Institute presented CMS with data indicating that health plans had not fully implemented the requirement to cover HIV pre-exposure prophylaxis (PrEP) as of 2021 despite guidance from CMS issued in 2020.[39] As a result, people have continued to be charged inappropriately for PrEP and related services, constituting a barrier to PrEP use and resulting in unnecessary HIV infections. We therefore urge the Department to strengthen enforcement and provide clearer guidance to ensure robust coverage of preventive services without cost-sharing.

Coverage of Prescription Drugs as EHB

Since 2013, HHS has required plans that must provide EHB to cover the greater of one drug per U.S. Pharmacopeia's Medicare Model Guidelines (USP MMG) class and category, or the same number of prescription drugs in each category or class as the state's EHB benchmark plan.[40] HHCAWG is encouraged that CMS is considering alternative prescription drug classification standards by which to determine whether a plan's formulary meets the minimum standards established in the EHB regulations, and urges CMS to strengthen the EHB prescription drug coverage rules by switching to the U.S. Pharmacopeia's Drug Classification (USP DC) system. HHCAWG also urges CMS to go further toward ensuring that consumers have meaningful access to affordable prescription drugs by requiring at minimum two drugs per category rather than one and/or establishing protected classes for which plans must cover all or substantially all drugs (with exceptions when generic substitutions are available), and by strengthening its enforcement of nondiscrimination standards in formulary design.

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[39] The AIDS Institute, Letter to CMS: Marketplace Insurance Plan Compliance with USPSTF Regulations Regarding Pre-Exposure Prophylaxis, (June 9, 2022), https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:745d0f26-703f-3ae5-9568-3fa04895cec9.

[40] 45 C.F.R. § 156.122; 78 Fed. Reg. § 12,845-46 (Feb. 25, 2013).

For a consumer, the strength of a plan's formulary lies largely in whether the plan covers a robust number and variety of drugs—including, in particular, any drugs that treat chronic conditions with which the consumer has been diagnosed—and whether the plan applies requirements that make these drugs unaffordable and inaccessible. Thus, it is critical that CMS use an accurate, accessible, and comprehensive drug classification system as a yard stick. Anything less permits plan formularies to pass administrative muster but provide little to no value to the consumer, and leaves people with chronic illnesses like HIV especially vulnerable to being unable access the medications that are most appropriate to manage their condition.

To this end, we believe the USP DC provides a better alternative than the USP MMG. The USP DC is publicly available, accessible, and subject to annual comment and review.[41] Conversely, although the USP MMG has long been familiar to insurance companies and federal and state regulators, it was not designed to serve as a benchmark for the average private insurance plan. Moreover, its use as a yardstick for Qualified Health Plans has been difficult for advocates to follow, with CMS releasing annual documents that summarize changes to the drug list, including "newly prescribable drugs."[42]

In its selection of a drug classification system, we urge CMS to consider whether the system's structure of categories and classes is comprehensive and detailed enough to ensure that plans cover enough *variety* of drugs to provide meaningful value to people living with chronic diseases such as HIV. Currently, the USP DC offers better classification of HIV drugs when compared to the USP MMG, because the USP DC treats anti-HIV combination therapies as their own class of drugs rather than grouping these therapies only according to their individual medication components.[43] This is crucial, because combination therapies (also known as single tablet regimens, or STRs) have been associated with better adherence, higher likelihood of viral suppression, and reduced risk of developing drug-resistant viral mutations.[44] Under the current EHB regulations and the USP MMG, a plan need not cover any STRs at all if it simply covers enough individual drug components to meet the requirements in 45 C.F.R. § 156.122. This is out of step with current widely recognized standards of HIV care.[45]

Regardless of which drug classification system CMS selects, the system must be subject to annual updates, with opportunity for public comment and review, as drugs are often introduced and discontinued in the U.S. market. A formulary must be nimble enough to incorporate newly approved

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[41] *See* USP Drug Classification, https://www.usp.org/health-quality-safety/usp-drug-classification-system. USP DC's website notes that it is "is intended for use by *any stakeholder* interested in a classification of drugs for use in formulary development or review." *Id.* (emphasis added).

[42] *See, e.g.*, Essential Health Benefits RX Crosswalk, Methodology for Plan Year 2022, https://www.qhpcertification.cms.gov/s/EHBRXCrosswalkMethodologyPY2022.pdf?v=1.

[43] *Compare* USP DC 2023 (reflecting an Anti-HIV Combinations classification) *with* USP MMG v. 8.0 (no comparable classification).

[44] *See, e.g.*, James Cutrell et al., *Single-Tablet Regimens in the Treatment of HIV-1 Infection*, 33 Fed. Pract. 24S (April 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375416/.

[45] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv.

drugs and to shed drugs that have been discontinued. When a standard formulary does not remove drugs that have been discontinued, plans are able to technically meet the EHB benchmark minimum requirements without offering sufficient value to consumers. For example, the USP MMG Version 8.0 (published February 1, 2020) removed two anti-Hepatitis C drugs, Technivie ((ombitasvir, paritaprevir, and ritonavir) and Daklinza (daclatasvir) from its formulary as these had been discontinued by the manufacturer.[46] However, the manufacturers of these drugs discontinued them in May 2018 (Technivie) and January 2019 (Daklinza).[47] Because these two drugs were in the same category and class (Anti-hepatitis C (HCV) Agents), plans would have been able to meet or largely meet the minimum prescription drug coverage standards in 45 C.F.R. § 156.122 by covering these two discontinued drugs, leaving consumers without any meaningful coverage of anti-hepatitis C agents they could actually obtain. We are also concerned that the USP DC notes that it does not include all drugs administered in a clinical setting given the availability of new potentially transformative prevention and treatment long-injectable options for HIV that currently require administration in a clinical setting. As noted above, we urge that additional requirements be applied to protect coverage of novel mechanisms for prevention and treatment.

Moreover, even the USP DC is not immune from overly broad drug classification categories. For example, neither the USP DC nor the USP MMG have any distinct category or class for anti-HIV drugs that can be used to *prevent* HIV infection.[48] These drugs, known as Pre-Exposure Prophylaxis (PrEP), are extraordinarily effective at preventing HIV transmission—when taken as prescribed, they reduce the risk of getting HIV from sex by about 99%.[49] Yet both the USP DC and the USP MMG are structured in such a way as to permit plans to exclude these drugs from their formularies, at least theoretically.[50] Both drug classification systems also employ only one category for Anti-HCV Agents, which includes drugs that have drastically different roles in treating HCV—including ribavirin, which is not effective alone and cannot be used by itself.[51] Thus, a plan that needs to meet a one-drug-per-class minimum can meet this

[46] USP MMG v 8.0 (showing changes).
[47] Da Hee Han, Two Hepatitis C virus Infection Treatments to be Discontinued, MPR (May 24, 2018), https://www.empr.com/home/news/two-hepatitis-c-virus-infection-treatments-to-be-discontinued/; OptumRx, Daklinza (daclatasvir) – Product discontinuation, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-recalls-shortages/drugwithdrawal_daklinza_2019-0107.pdf.
[48] USP MMG v. 8.0; USP DC 2023.
[49] Centers for Disease Control and Prevention, PrEP Effectiveness, https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html#:~:text=How%20long%20does%20PrEP%20take,21%20days%20of%20daily%20use..
[50] Under ACA § 2713(a)(a) a private insurer offering individual health insurance would be required to cover PrEP without cost sharing. *See id.*; U.S. Preventive Services Task Force, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. However, allowing plans not to include medications approved for PrEP on their formularies creates needless hurdles for consumers.
[51] USP MMG v. 8.0; USP DC 2023.

requirement by simply covering ribavirin, which could prevent its members from accessing a full, effective course of HCV treatment.[52]

For these reasons, HHCAWG urges CMS to update the EHB prescription drug regulations to require, at a bare minimum, coverage of *at least two drugs per category and class*. HHCAWG also strongly recommends that CMS go further, and consider applying to EHB the requirement applicable to all Medicare Part D plans to cover all or substantially all drugs within six protected classes with exceptions for generic substitutions, including antiretrovirals.[53] Such rules help to "to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations," and decrease the likelihood that Part D plans will be designed in such a way as to discourage beneficiaries reliant on these drugs from enrolling in the plans.[54]

Finally—and especially if CMS does not institute protected classes of drugs as described above—we also urge CMS to take a more active role in working with states that operate their own Exchanges or that assume responsibility for certifying QHPs to better ensure plans adequately cover prescription drugs. Meeting the benchmark number of drugs per class and category is not sufficient; plans must ensure that the design of their benefits do not discriminate based on an individual's disability or other health condition.[55] While we appreciate that CMS clarified its expectations around nondiscrimination protections in the Notice of Benefit and Payment Parameters for 2023,[56] many states have approved QHPs that place most or all covered drugs used to treat a certain chronic condition on the most expensive formulary tier and/or subject all covered drugs to burdensome administrative requirements. Examples include:

- In Massachusetts, a review of WellSense's formulary for coverage of Anti-HCV Agents shows that the all covered first-line Direct-acting Antivirals (DAAs) (including two generics) are listed on the highest tier, are subject to specialty drug requirements, and are subject to prior authorization requirements.
- In Illinois, a review of Quartz's formulary for coverage of Anti-HCV Agents showed that all covered first-line DAAs were covered on the highest tier, are subject to specialty drug requirements, and are subject to prior authorization requirements.

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[52] While there are regulations that serve to discourage this kind of egregious formulary design, *see, e.g.*, 45 C.F.R. § 156.125(a); 45 C.F.R. § 156.122(a)(3) (establishing standards for plan pharmacy and therapeutics committees, including their responsibility to ensure that a plan's formulary "[c]overs a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states") as discussed in the text below, QHPs continue to be certified despite engaging in adverse tiering. Clearly, more robust EHB standards and enforcement of those standards is necessary to ensure that consumers, particularly those with chronic conditions, can access the medications they need.

[53] *See* Affordable Care Act § 3307(a); Medicare Prescription Drug Benefit Manual Chapter 6, § 30.2.5.

[54] Medicare Prescription Drug Benefit Manual Chapter 6, § 30.2.5.

[55] 45 CFR § 156.125(a).

[56] 87 Fed. Reg. 27,296 (May 6, 2022).

Federal regulations indicate that "[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's… disability, … or other health conditions."[57] Discriminatory coverage of an EHB category can lead to overt consumer harm when individuals living with specific chronic conditions are unable to obtain any key medications in an affordable and accessible manner. We were pleased to see that CMS's 2024 Draft Letter to Issuers in Federally-facilitated Exchanges included a statement of CMS's intent to begin conducting adverse tiering review, including for HIV and HCV drugs,[58] and urge CMS to work with states and review federal Marketplace plans to ensure that QHPs are not inappropriately certified as providing coverage of EHBs when they do so in violation of nondiscrimination standards.

Conclusion

We appreciate HHS officials and CMS leaders efforts to improve access and affordability of health care. Please feel free to reach out to Rachel Klein, The AIDS Institute at rklein@taimail.org; Liz Kaplan, Center for Health Law & Policy Innovation, ekaplan@law.harvard.edu, and Andrea Weddle, HIV Medicine Association, aweddle@hivma.org should you have any questions. Thank you very much for your consideration of our comments.

Sincerely,

AHF
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
AIDS United
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 Dental Alliance
HIV Medicine Association
iHealth
International Association of Providers of AIDS Care
Lambda Legal
National Coalition of STD Directors
NASTAD
Positive Women's Network-USA
Prevention Access Campaign

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[57] 45 CFR § 156.125(a).
[58] 2024 Draft Letter to Issuers in Federally-facilitated Exchanges (December 12, 2022), https://www.cms.gov/files/document/2024-draft-letter-issuers-508.pdf.

San Francisco AIDS Foundation
The AIDS Institute
U=U plus
Vivent Health