FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

February 19, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: HHS Comments to Notice of Benefit and Payment Parameters for 2020

To Whom It May Concern:

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 healthcare and support services. We appreciate the opportunity to provide comments on the proposed Notice of Benefit and Payment Parameters for 2019.

Standards and protections governing the ACA-compliant individual market must ensure access to comprehensive and affordable coverage for people living with HIV, HCV, and other chronic conditions. To provide meaningful access to care for people living with HIV and others living with chronic conditions, we urge HHS to consider the recommendations and comments detailed below.

PRESCRIPTION DRUG ACCESS

The HIV prevention and treatment landscape and standard of care have experienced critical advances over the last decade. Many of the newer antiretrovirals achieve more rapid and durable suppression of HIV, have fewer side effects, and can improve adherence through reduced pill burden. Based on a conclusive body of evidence, the recommended standard of care is now to start individuals living with HIV on treatment soon after diagnosis with the most effective, best-tolerated regimen. Not only will this optimize individual health outcomes, but because individuals who are virally suppressed cannot transmit the virus, ensuring early access to the appropriate treatment regimen is critical for public health efforts to end new HIV infections. In addition, the FDA approved the first biomedical intervention using an antiretroviral drug (Pre-Exposure Prophylaxis or PrEP) in 2012. PrEP is highly effective at

preventing acquisition of HIV and recently received a draft Grade "A" recommendation from the U.S. Preventive Services Task Force. We now also have curative therapy for hepatitis C (HCV) through direct acting antivirals. While we support efforts to ensure access to the most cost-effective treatment options, we must also ensure continued access to clinically recommended treatment regimens, particularly for complex conditions like HIV and HCV.

Manufacturer Co-pay Assistance (§ 156.130(h)(2))

While we recognize the need to address rising drug prices, access to medications is critically important for people living with HIV, people who are at higher risk of HIV, and people living with HCV. However, because of high co-payments and co-insurance attached to these medications, affordability continues to be a major barrier to meaningful access. Manufacturer co-pay cards have been essential to ensure uninterrupted access to these medications, particularly because suitable generic alternatives are not currently available for PrEP and for the treatment of HIV and HCV. While some generic alternatives are available for HIV treatment regimen components, the full regimens recommended in the HHS HIV treatment guidelines still involve at least one brand-name drug with no generic equivalent.

We are very concerned that explicitly allowing an issuer not to count certain third-party payments towards a beneficiary's deductible and out-of-pocket maximum is contrary to other provisions of the ACA. The ACA defines cost sharing as "any expenditure required by or on behalf of an enrollee with respect to essential health benefits" (45 CFR § 155.20). Therefore, any payments made on behalf of the enrollee, such as manufacturer copay cards, should count towards cost sharing. The ACA also includes an annual out-of-pocket maximum for cost sharing (45 CFR § 156.130). When plans and pharmacy benefit managers (PBMs) implement co-pay accumulator policies, they are collecting far more than the ACA's annual out-of-pocket maximum. In fact, plans/PBMs could collect thousands more dollars above the annual out-of-pocket maximum over the course of a plan year because they collect pre-deductible payments from the manufacturer co-pay cards until the consumer exhausts the allowed annual amount for the co-pay assistance program. (See example provided in NASTAD's Co-Pay Accumulator Fact Sheet, showing that plans are collecting well beyond the statutory annual out-of-pocket maximum). Only after the manufacturer co-pay coupon program is exhausted will the issuer start counting a consumer's cost sharing toward the deductible and out-of-pocket maximum. We believe these practices should be prohibited.

If HHS retains this policy, we appreciate that the proposed language limits the use of co-pay accumulator policies to situations where there is a generic equivalent available and believe that will help to ensure that individuals with no alternative to a brand-name medication are able to afford their medications. However, we are concerned that there may be instances where a generic medication is available, but the price is not significantly lower than the brand-name drug. In those instances, there are no cost-savings garnered from disincentivizing the use of a manufacturer co-pay card. We urge HHS to limit the use of policies prohibiting manufacturer co-pay cards from counting toward a person's deductible and out-of-pocket maximums only in

instances where there is both a generic, clinically equivalent and effective medication and the medication is at a lower cost-sharing tier than the brand-name drug.

We also urge HHS to clarify that the proposed rule would effectively prohibit use of co-pay accumulator policies when there is not an interchangeable, lower cost generic alternative. Both individual market and employer-based plans are currently implementing these policies, with no protections for individuals who require access to a brand-name drug with no generic equivalent. We believe that strong federal and state enforcement will be necessary to ensure that vulnerable populations are protected. In addition, plans should be required to publish the existence of a co-pay accumulator policy in their Summary of Benefits and Coverage (SBC) to ensure that consumers are able to make informed choices about the best plan for them. Language must be very explicit as to the issuer or PBM's third-party payment policy. For example, while Molina's language is found on the SBC, it simply states that "coupons or any other form of third-party prescription drug assistance will not apply toward any deductibles or annual out-of-pocket limits." There are certain third-party payments, including those made by the Ryan White Program, that issuers must accept (45 CFR §156.1250), and overly broad language like the example provided could dissuade people living with HIV and others who rely on these third-party assistance programs from signing up from coverage.

Finally, rising consumer costs for prescription drugs continues to be a significant barrier to access, particularly with increasing use of high-deductible plan designs. We urge HHS to also consider policies that protect consumers from these high costs, including reinstating standardized plan designs with a low deductible option and capping co-pays.

Changes to Non-Discrimination Review (45 CFR §156.125)

Access to medication-assisted treatment (MAT) is essential to our efforts to combat the opioid epidemic. We appreciate the acknowledgment that there are issuers who are using plan designs and utilization management practices to limit access to MAT, even when these drugs are included on a plan's formulary. We believe that requiring a plan to show that utilization management associated with MAT is clinically indicated will help to reduce discriminatory practices. We urge HHS to take a larger role in monitoring and enforcing all non-discrimination requirements with regard to formulary design, including ensuring that states are using appropriate formulary review tools and responding to instances of formulary designs that are not based on clinical guidelines.

Cost-sharing Requirements for Generic Drugs (45 CFR §156.130)

While we applaud efforts to rein in rising drug costs, we are concerned about policies that focus solely on limiting formulary access. For complex conditions like HIV, treatment regimens are highly individualized, particularly for those who have been living with the disease for a long time or have other co-morbidities. Even as generic components become available, there is still no currently approved treatment regimen that does not depend on at least one brand-name drug. We are concerned that allowing issuers to deem certain brand-name drugs not a part of the Essential Health Benefits (meaning that costs paid toward them will not count toward

annual cost-sharing limits and they will be subjected to annual and lifetime limits) could cause consumer confusion and leave consumers with surprise, unaffordable prescription drug costs. We also believe that it will be difficult to administer this provision because of the discretion involved in defining what constitutes a "medically appropriate generic equivalent" drug.[1] While the prescription drug exceptions process specified in 45 CFR §156.122(c) has been a critical provision, it is not a replacement for front-end protections that ensure access to clinically appropriate drugs, particularly for complex conditions. We believe there are other ways to promote cost-effective prescription drug access, for instance through encouraging value-based plan designs.

Mid-Year Formulary Changes

Similarly, while we support the ability of plans to add newly available drugs in the middle of a plan year – both new generic formulations and brand-name drugs – we believe that individuals who are on established regimens need additional protections to ensure that they do not experience harmful treatment disruptions. We urge HHS to prohibit issuers from imposing negative formulary changes (including removing prescription drugs from the plan's formulary absent safety issues, moving prescription drugs to a higher formulary tier, imposing higher cost-sharing on formulary tiers, or placing new prior authorization or step-therapy requirements on prescription drugs) during the plan year. Absent limited circumstances, including FDA approval of a new drug, we urge HHS to prohibit mid-year formulary changes that could cause treatment disruptions.

Comments for Future Rulemaking on Prescription Drug Access

While HHCAWG supports regulatory efforts to rein in increases in prescription drug costs, we believe that policy proposals must preserve consumer protections and access to clinically appropriate treatment regimens. This is particularly true for complex conditions like HIV, and we believe that any proposal that impacts formulary design must ensure that access to HIV medications is based on the federal HIV treatment guidelines.[2]

We are concerned that policy proposals like therapeutic substitution will not be able to take into account the individualized nature of HIV treatment. HIV treatment regimens are complex, involving combinations of multiple medications. Choosing the appropriate regimen is necessarily individualized as a number of patient and virus-specific factors are relevant. Requiring an individual to demonstrate poor adherence, experience a serious adverse event, or experience virologic failure on a regimen not recommended by the clinical provider, or delaying

[1] HHCAWG considers generic drugs to be therapeutically equivalent if they contain the same active ingredients as the innovator product, including coformulations; have the dosage form and route of administration; are identical in strength; have the same indications of use with demonstrated bioequivalence; meet the same standards for identity, strength, purity, and quality; and are manufactured under the same standards that FDA requires for innovator products.

[2] Department of Health and Human Services, Federal HIV/AIDS Practice Guidelines, http://aidsinfo.nih.gov/guidelines.

access to treatment by imposing unnecessary prior authorization hurdles, will have disastrous individual and public health effects and will result in additional costs to the healthcare system.[3] We also recognize that newer formulations of older drug or biologic products – including those with similar routes of administration, such as oral coformulations and single-tablet regimens – can be clinically important additions to standards of care, including reductions in pill burden. It may, therefore, be impossible to truly substitute one regimen for another.

Similarly, we believe that any reference pricing policies must include consumer access protections. HHCAWG shares the Administration's interest in reference pricing as one potential strategy to control prescription drug spending and appreciates the need for continued exploration of the opportunities and risks of implementing and incentivizing reference-based drug pricing. As per the proposed rule, reference-based pricing occurs "when an issuer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price." Another reference-based pricing scheme to explore, through legislation, is extending inflation penalties to new drugs that drastically exceed the average inflation-adjusted initial average manufacturer prices (AMPs) of widely-used drugs in the same therapeutic class,[4] thereby shifting the burden of complex and evolving cost-effectiveness determinations away from consumers and health care providers and on to manufacturers.

NAVIGATOR PROGRAM STANDARDS (45 CFR §§ 155.210 and 155.215)

The proposed rule would weaken standards related to the Navigator program by making certain post-enrollment Navigator duties optional and eliminating important training requirements. We urge HHS to maintain current Navigator program standards to ensure that consumers have robust access to impartial, skilled assistance both during and after enrollment.

People living with HIV have experienced significant gains in insurance coverage under the ACA, often with the help of Navigators. Several Navigator grantees were AIDS Service Organizations (ASOs), or other organizations that identified people living with HIV as a focus population. Given historical exclusion of people living with HIV from the health insurance market, having HIV-focused Navigators serving consumers at a place where they are already receiving services fosters trust between consumers and assisters and facilitates smoother enrollment. Additionally, Navigator entities serving people living with HIV often forge close relationships with community partners, such as Ryan White clinics, health departments, and medical providers, which increases the likelihood that people living with HIV will remain insured and engaged in care. For example, as described in a Kaiser Family Foundation survey of HIV-focused

[3] Studies have found that even when step therapy and prior authorization reduced pharmacy costs, emergency room and hospitalization costs increased. See, e.g., Rashad I. Carlton, "Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy," 2 American Journal of Pharmacy Benefits 50, 56–7 (2010).
[4] Fair Pricing Coalition. Tackling Drug Costs: A 100-Day Roadmap. December 2016. https://fairpricingcoalition.org/wp-content/uploads/2016/12/Tackling-Drug-Costs-A-100-Day-Roadmap-FINAL.pdf.

Navigator entities, Navigator grantees are well positioned to work with ADAP to assess insurance options and transition clients to new plans in cases where an issuer serving a significant portion of ADAP clients leaves the market.[5] This is just one example of the many ways in which HIV-focused Navigators have formed meaningful relationships with other stakeholders to provide invaluable support for people living with HIV in their communities. We are opposed to any scaling back of the Navigator program that may jeopardize access to enrollment assistance for people living with HIV.

As HHS has acknowledged in prior rulemaking, Congress anticipated that consumers would require assistance beyond the application and enrollment process and therefore established requirements to facilitate ongoing relationships between Navigators and consumers throughout the year after initial enrollment.[6] Additionally, the ACA requires Navigators to distribute fair and impartial information concerning enrollment in QHPs and the availability of premium tax credits and cost-sharing reductions, and also to facilitate enrollment in qualified health plans.[7] These functions are not only required by statute, but they are integral to the core purpose of the Navigator program. The required Navigator functions listed in 45 CFR 155.210(e)(9), which HHS now seeks to make optional, set standards for Navigators in adhering to the statutory requirements. As HHS has previously noted, helping consumers understand their appeal rights in the event of an adverse eligibility determination, assisting with the process of completing and submitting appeal forms, educating consumers about the individual shared responsibility requirement and exemptions, helping consumers with Exchange-related components of the premium tax credit reconciliation process, providing referrals to tax experts, and helping consumers understand the kinds of decisions they will need to make in selecting and using coverage are essential to fulfilling Navigators' statutory requirements to facilitate enrollment and help consumers obtain fair and impartial information about enrollment.[8] We therefore object to the proposed changes to 45 CFR 155.210(e)(9) and corresponding provisions in 45 CFR 155.210(b)(2), related to Exchange training standards, and urge HHS to follow the letter of the law by maintaining robust *mandatory* requirements for Navigator programs. In addition to the questionable legality of this proposal, we are concerned that eliminating these important Navigator functions will harm consumers by reducing access to post-enrollment assistance such as appeals, reconciliation, and health literacy. People living with HIV and other chronic conditions must have robust access to these types of services because they have complex medical needs and often require high-cost treatments, which makes them especially vulnerable to claim denials, high cost-sharing, confusion about plan design, and uncertainty about the financial and tax implications of their coverage and care. Rather than weakening Navigator standards to accommodate cuts to Navigator program

---

[5] Lindsey Dawson and Jennifer Kates, "Implications of Navigator Funding Changes on People with HIV: Navigator Perspectives," Kaiser Family Foundation (Dec. 2017), available at http://files.kff.org/attachment/Issue-Brief-Implications-of-Navigator-Funding-Changes-on-People-with-HIV-Navigator-Perspectives.

[6] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 80 Fed. Reg. 75,487, 75,520-21 (Dec. 2, 2015).

[7] Patient Protection and Affordable Care Act, 42 U.S.C. § 18031(i)(3)(B), (C) (2010).

[8] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 80 Fed. Reg. at 75,520-23.

funding, we further urge the Department to restore Navigator funding to enable Navigator programs to continue providing impartial, skilled assistance to consumers in a wide variety of areas both during *and after* enrollment.

We are additionally concerned about the proposal to weaken content standards for Exchange-developed trainings targeted at Navigator and non-Navigator personnel, including Certified Application Counselors (CACs). Under the proposed rule, the current list of 15 specific and detailed FFE Navigator training topics at 45 CFR 155.215(b)(2) would be reduced to four broad subject areas that fail to adequately capture the scope of key Navigator duties. Navigators and non-Navigator consumer assistance personnel provide essential support to consumers related to QHP operations, appeal rights, the range of insurance affordability options such as Medicaid and CHIP, eligibility requirements for premium tax credits and cost-sharing reductions and how this financial assistance impacts consumer costs, basic health insurance concepts and the value of insurance, and plan comparison—all of which HHS now proposes to remove from the list of mandatory training topics. Repealing these specific training standards would drastically hamper the ability of Navigator programs to fulfill their statutory requirements of facilitating enrollment and providing fair, impartial information to consumers. Accurate and comprehensive enrollment information and assistance is particularly important for people living with HIV and other complex conditions. The proposal suggests that weakening these standards would enable Exchanges to focus on training areas they determine to be most relevant to the populations they serve. However, any given Exchange serves a broad range of communities with varied and diverse needs; it is therefore crucial that Navigator and non-Navigator personnel serving consumers on the ground are prepared to meet *all* the needs of their unique communities, which will vary significantly across an Exchange's service area.

For example, HIV-focused Navigators and non-Navigator personnel have unique expertise related to which health plans work best for people living with HIV in terms of access to medications, providers, and interoperability with Ryan White.[9] Navigators and non-Navigator staff help all consumers choose plans where their providers are in-network and their medications are covered, and this is especially important for people living with HIV who often require high-cost medications and have longstanding relationships with their medical providers. HIV-focused enrollment personnel help people living with HIV ensure that plans cover prescribed treatments and also have affordable cost-sharing. People living with HIV who receive care by an experienced HIV provider have better outcomes and receive more cost effective care.[10] [11]Affordable coverage is a key determinant in whether a person will stay engaged in care, and there are compelling individual and public health reasons for ensuring that people living with HIV have access to skill, unbiased support in choosing plans, navigating insurance affordability programs, and using their coverage. We are concerned that an Exchange could

[9] Dawson and Kates, *supra* note 5, at 4-5.

[10] Horberg, et al. Influence of provider experience on antiretroviral adherence and viral suppression. HIV AIDS (Auckl) 2012;4:125-133.

[11] Weiser, et al. Service Delivery and Patient Outcomes in Ryan White HIV/AIDS Program–Funded and –Nonfunded Health Care Facilities in the United States. JAMA Intern Med. 2015 Oct; 175(10): 1650–1659.

easily exercise the "flexibility" granted under the Department's proposal to eliminate training related to serving people living with HIV.

Removal of the requirement that Navigator and non-Navigator personnel ensure physical and other accessibility for people with a full range of disabilities runs contrary to HHS's stated goal of maintaining strong supports for vulnerable populations. This requirement ensures that Navigator and non-Navigator personnel can communicate with and assist people living with disabilities, identify issues that are central to health insurance eligibility and needs of people living with disabilities, and provide accurate and understandable coverage information and additional referrals. We urge HHS to work towards strengthening, not weakening, disability literacy among Navigator and non-Navigator personnel.[12]

We also urge HHS to reconsider its proposal to eliminate training requirements related to tax implications of enrollment decisions. This, coupled with the proposal to make optional Navigator duties related to tax referrals and consumer support with premium tax credit reconciliation, raises significant concerns that consumers will make important health-related decisions without understanding the financial and tax implications. Navigators provide crucial support to consumers in understanding the basic concepts of tax credits and reconciliation, navigating tax forms and filing requirements, and obtaining expert tax advice. As HHS notes in its proposed rule, 87 percent of Exchange enrollees receive advance premium tax credits covering an average of 87 percent of their premium. Given that availability of premium tax credits heavily impacts enrollment decisions, and the fact that the overwhelming majority of HHS enrollees receive premium tax credits, providing competent information to consumers on this subject is an essential element of Navigator and non-Navigator assistance and should remain a mandatory component of training. This type of tax assistance is particularly important for Ryan White Program clients, who typically have to coordinate receipt of Ryan White Program assistance with tax reconciliation requirements for premium tax credits.

The ACA additionally requires Navigator programs to provide information in a manner that is culturally and linguistically appropriate to the needs of the communities served by the Exchanges, while both the ACA and federal civil rights laws require Exchanges to provide language services for people with limited English proficiency.[13] We are concerned that the proposal to remove these areas from the training module content standards will limit the ability of Navigator programs to fulfill these statutory requirements. For people living with or at risk of HIV, this is especially concerning due to historical stigma against HIV and perceived "risky behaviors" that increase likelihood of HIV transmission. It is important that Navigators serving people living with HIV or other chronic conditions are trained to create a welcoming, safe environment. We are opposed to any weakening of Navigator program standards that may

[12] National Disability Navigator Resource Collaborative, "Guide to Disability for Healthcare Insurance Marketplace Navigators," available at https://nationaldisabilitynavigator.org/wp-content/uploads/Materials/Disability-Guide.pdf.

[13] Patient Protection and Affordable Care Act, 42 U.S.C. § 18031(i)(3)(E) (2010).

jeopardize culturally competent access to enrollment assistance for people living with or at risk of HIV.

ABILITY OF STATES TO PERMIT AGENTS AND BROKERS TO ASSIST QUALIFIED INDIVIDUALS, QUALIFIED EMPLOYERS, OR QUALIFIED EMPLOYEES ENROLLING IN QHPS (45 CFR § 155.220)

We are concerned about the proposal to expand the types of application assisters that are not subject to licensure requirements but that nonetheless help consumers apply for financial assistance and coverage through the Exchange. Staff employed by QHPs and other direct enrollment entities are not an adequate substitute for the impartial assistance that consumers receive from Navigators and CACs. Impartial assistance is especially important for people living with HIV and other chronic conditions, for whom choosing a health plan and discussing their care needs is both sensitive and also carries significant financial implications for the consumer. It is crucial that people living with HIV receive unbiased information about cost-sharing and coverage, from assisters that have no financial stake in which plans the enrollees ultimately choose. We urge HHS to instead increase Navigator and CAC capacity by restoring Navigator program funding that has been drastically cut in recent years.

We are concerned that, if HHS were to permit Navigators and CACs to use web broker websites as proposed, this would undermine the impartial nature of assistance provided by these entities. Although HHS proposes to prohibit web broker websites from displaying QHP recommendations based on compensation received from issuers, the proposal would not prohibit web brokers from implicitly making recommendations—for example, by listing QHPs that the web broker does not contract with at the bottom of its plan listings, or by providing more robust plan information for QHPs with which the web broker does contract. This renders the prohibition on explicit recommendations toothless, since there are no apparent limits on web brokers' ability to employ such implicit recommendations. Navigators and CACs are statutorily required to provide impartial advice to consumers, and consumers benefit significantly from this impartiality. We are opposed to any policy that would compromise the impartiality of assistance that consumers receive from Navigators and CACs; we are therefore opposed to this proposal, which would allow Navigators and CACs to rely upon biased information when assisting consumers. Additionally, we believe that all unassisted consumers accessing web broker websites should be able to view QHP information free of any implicit or explicit recommendations. This proposal will create confusion because unassisted consumers will not have guidance from an impartial Navigator or CAC who understands how information on the web broker website is organized.

While we support the proposal to limit web broker marketing of non-QHP products to consumers during the eligibility and plan selection process, we are concerned that information about non-QHP plans will still be displayed before the consumer completes the shopping experience. This is especially important in cases where the web broker website displays non-ACA-compliant products; these products may have dramatically lower costs relative to the QHPs the consumer has just seen, and there is great risk of misleading consumers that the lower cost non-compliant products are comparable to the ACA-compliant QHPs. For people

living with HIV and other chronic conditions, these non-compliant products are extremely inadequate and could lead to disastrous consequences ranging from claim denials, post-claims underwriting, caps on benefits, condition exclusions, or plan rescission. We urge HHS to require web broker website to very clearly indicate that non-QHP products marketed before the consumer has completed enrollment may have fewer benefits and higher out of pocket costs relative to the QHP the consumer has already chosen.

We would additionally like to echo concerns raised in comments to previous rulemakings related to expansion of direct enrollment, which we believe are still relevant but are not addressed in the proposal at hand.[14] Specifically, we ask HHS to ensure that consumers who enroll through an enhanced direct enrollment pathway still receive from the Exchange important notices and other information that impacts their finances and coverage, since these consumers will be able to complete their application and enrollment without redirecting to Healthcare.gov. We are additionally concerned that the proposal does not specify how sensitive consumer information shared with web brokers will be protected. The information needed to determine a person's eligibility for tax credits is highly sensitive, and the proposal appears to make this information available to numerous additional entities without a clear plan for how privacy and security requirements would be met.

SPECIAL ENROLLMENT PERIODS (45 CFR § 155.420)

We support the Department's proposal to add a Special Enrollment Period (SEP) for consumers enrolled in off-Exchange coverage who become newly eligible for APTCs due to a decrease in household income. However, given recent federal rulemaking expanding availability of non-ACA-compliant products such as short-term limited duration insurance and association health plans (AHPs), we request the Department extend this new SEP to consumers who have enrolled in these non-compliant types of coverage as well. Consumers who purchase these products will often do so because their incomes exceed the threshold for APTC eligibility; this is exacerbated by the fact that, as we pointed out in our comments to previously proposed rulemakings expanding access to short-term plans and AHPs[15], proliferation of these non-compliant products will ultimately lead to higher costs in the ACA-compliant market over time. This creates a vicious cycle: consumers buy non-compliant plans (for example, because they are unaware that these plans are non-compliant, or because they have minimal health needs), which causes prices on the ACA-compliant market to increase, which prices enrollees with incomes above 400% FPL out of the ACA-compliant market and leads to even more enrollment in non-compliant plans. Additionally, the Department's other proposals within this rulemaking may further increase enrollment in non-compliant products; if the proposed rule is finalized as

[14] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 61,456 (proposed Sept. 6, 2016), comment submitted by Center on Budget and Policy Priorities on October 11, 2016, https://www.regulations.gov/document?D=CMS-2016-0148-0574.

[15] Short-Term, Limited Duration Insurance, 83 Fed. Reg. 7,437 (proposed Feb. 21, 2018), comment submitted by HIV Health Care Access Working Group on May 16, 2018, https://www.regulations.gov/document?D=CMS-2018-0015-8674; Definition of "Employer" Under Section 3(5) of ERISA—Association Health Plans, 83 Fed. Reg. 614 (proposed Jan. 5, 2018), comment submitted by HIV Health Care Access Working Group on March 30, 2018, https://www.regulations.gov/document?D=EBSA-2018-0001-0450.

currently written, consumers will be more likely to receive biased assistance when choosing a plan and are more likely to be steered towards non-compliant products displayed on web broker websites. By excluding consumers who purchase non-compliant plans from this new SEP, the Department punishes consumers who purchase products that the Department itself has sought to promote. We are especially concerned that people living with HIV and other chronic conditions who purchase non-compliant products will be left without protection if their income decreases, further compounding the financially ruinous consequences they will already face just by enrolling in these sub-standard plans. While we support the proposal to expand the SEP prior coverage requirement to include additional types of coverage not independently designated as MEC under 26 CFR 1.5000A-1(b), we believe that the newly proposed SEP should additionally be extended to consumers who purchase non-ACA-compliant coverage that does not qualify as MEC.

PREMIUM ADJUSTMENT PERCENTAGE (45 CFR § 156.130)

HHCAWG strongly opposes this change. We are concerned that the proposed changes to the methodology HHS uses to calculate the premium adjustment percentage will have not only negative consequences for everyone purchasing coverage through the Exchanges, but will have particularly harmful effects for people living with HIV, HCV, and other chronic health conditions. The premium adjustment percentage affects the operation of multiple consumer protections enshrined in the ACA that limit the cost of health care for people living with HIV, and we urge HHS to reconsider reducing the scope of these protections with this modification.

As HHS's own estimates show, this change will negatively impact consumers in a number of ways. First, as noted later in the proposed rule, this methodology will lead to steeper increases in the maximum annual limitation on cost sharing. For example, the proposed annual limitation on cost sharing using the premium adjustment percentage calculated under the proposed methodology for individuals is $8,200 and $16,400 for families, compared to $8,000 and $16,000 respectively under the existing methodology.[16] For many individuals living with HIV, HCV, and other chronic health conditions, the annual limitation on cost sharing already does not provide sufficient protections due to the high cost sharing required to access prescription drugs and key services for HIV/HCV care and treatment. For example, an analysis of Qualified Health Plans sold in Georgia demonstrates that people living with HIV and/or HCV are often required to meet the annual limitation on cost sharing to access medically necessary prescription drugs, and frequently reach the limitation early into the benefit year.[17]

Second, modifying the methodology would, as estimated by HHS, result in net premium increases of approximately $181 million in net premiums per year, increasing the already heavy

[16] Center on Budget and Policy Priorities, "Change to Insurance Payment Formulas Would Raise Costs for Millions With Marketplace or Employer Plans" (Jan. 2019) available at, https://www.cbpp.org/research/health/change-to-insurance-payment-formulas-would-raise-costs-for-millions-with-marketplace.

[17] Center for Health Law and Policy Innovation, "Georgia Marketplace 2019 QHP Assessment" (Feb 2019) available at https://www.chlpi.org/wp-content/uploads/2013/12/Georgia_QHPReport_2_8_2019.pdf.

financial burden mentioned above. Additionally, because the premium adjustment percentage is used to calculate the portion of premiums consumers are responsible for paying, the proposed change would result in a reduction of advanced premium tax credits that many individuals living with HIV/HCV rely on to afford coverage. HHS estimates that tax credits would be reduced by $1.9 billion between 2020-2023. As an example, in 2020 this would result in an increase of $98 in premiums for an individual making $40,000/year.

Finally, overall enrollment on the Exchanges will decrease as the cumulative result of these changes. HHS estimates that 100,000 people are expected to drop health coverage from the Exchanges per year between 2020-2023. Many of these individuals will be without another option for affordable coverage. Additionally, this threatens to harm the ACA's risk pool as consumers are priced out of coverage leading to further premium increases.

The existing methodology that excludes Exchange premiums from the calculation of average per enrollee premiums for purposes of the premium adjustment percentage calculation was put in place by HHS due to a recognition that individual market premiums in the ACA-compliant market would likely be unstable as insurers adjusted to new rules.[18] Particularly in light of the recent regulatory changes expanding the availability of association health plans, short-term limited-duration coverage, and other non-ACA-compliant forms of coverage, insurers are still facing considerable uncertainty as to market stability. In light of this uncertainty and the negative consequences this modification would have on people living with HIV, HCV, and other chronic health conditions, we urge HHS to reconsider and maintain the existing methodology.

HHS RISK ADJUSTMENT (45 CFR § 153.320) – UPDATES TO THE RISK ADJUSTMENT MODEL CALIBRATION

We thank HHS for seeking comment on ways to better anticipate and more precisely adjust the drug categories used in the risk adjustment models. We continue to support the use of prescription drug utilization as an input into the risk adjustment model. For patients with HIV and other chronic illnesses who have at least one insurance claim related to that illness within a year, diagnostic data is sometimes not available for such claims for various reasons and using prescription drug data will improve the risk adjustment model. We support HHS routinely evaluating the drug diagnosis pairs in the model, as this will discourage issuers from adjusting their reimbursement for certain drugs to drive prescribing patterns more favorable to the risk adjustment model.

However, we urge HHS to include Pre-Exposure Prophylaxis (PrEP) on the RXC-HCC list related to HIV even for individuals who do not have HIV. PrEP is used by people who do not have HIV to prevent them from contracting the virus, and recently received a draft Grade "A" recommendation from the U.S. Preventive Services Task Force (USPSTF) for people at high risk

[18] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015, 79 Fed. Reg. at 13,801.

of acquisition.[19] Given PrEP's effectiveness at preventing HIV transmissions and USPSTF's recommendation that will soon translate into a no cost sharing coverage obligation for insurers, HHS should ensure that insurers do not have an incentive to steer individuals taking PrEP away from their plans. According to the March 2016 CMS whitepaper discussing ways to improve the risk adjustment model, one of the reasons to include prescription drug utilization data in the risk adjustment model is that using such data will "mitigate the financial disincentive to prescribe expensive medications" and thereby be "fairer to plans that enroll many people who require expensive drugs".[20] Including PrEP on the RXC-HCC list for people who do not have HIV will achieve this goal as insurers will receive credit for PrEP in the risk adjustment model. In the long-term, this preventive approach will yield public health benefits as well as cost savings.

Thank you for the opportunity to comment on this proposed rule. Please contact Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@nastad.org or Phil Waters at pwaters@law.harvard.edu with the Center for Health Law and Policy Innovation if we can be of assistance.

Respectfully submitted by:

ADAP Educational Initiative | AIDS Alabama | AIDS Action Baltimore AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health AIDS Resource Center of Wisconsin | Bailey House, Inc. | Black AIDS Institute | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Georgia AIDS Coalition | Harm Reduction Coalition | HealthHIV | HIV Medicine Association | Housing Works | Human Rights Campaign | Legal Council for Health Justice | Michigan Positive Action Coalition | Minnesota AIDS Project | National Alliance of State and Territorial AIDS Directors | National Latino AIDS Action Network | NMAC | Positive Women's Network - USA | Project Inform | Rocky Mountain CARES | San Francisco AIDS Foundation | SisterLove | Southern AIDS Coalition | Southern HIV/AIDS Strategy Initiative | St. Louis Efforts for AIDS | The AIDS Institute | Treatment Access Expansion Project | Thrive Alabama

[19] U.S. Preventive Services Task Force, "Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis" (2018) available at, https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[20] Centers for Medicaid and Medicaid Services, "HHS-Operated Risk Adjustment Methodology Meeting – Discussion Paper" (Mar. 24, 2016) available at, https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.