FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

March 2, 2020

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9916-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Notice of Benefit and Payment Parameters for 2021

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 2021 (the Proposed Rule).

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.

Automatic Re-Enrollment

HHCAWG strongly supports maintaining a consumer-friendly automatic re-enrollment process to ensure continuous healthcare coverage for those who do not take action to select a new plan. Roughly 3.4 million people, or 30 percent of individuals who purchased their health insurance through the ACA rely on this practice, which also works to streamline the health insurer process, and has also helped maintain a robust risk pool enrolled in the marketplace. [1]

Continuity of care is of the utmost importance for people living with HIV and HCV. An interruption in coverage, and access to health care can be detrimental resulting in irreversible disease progression, developing treatment resistance, and even death. The proposed changes to the auto reenrollment process in the 2021 NBPP stands to harm thousands, if not millions, of low-income individuals who receive advance payments of the premium tax credit (APTC) amounting to a $0 premium, and rely on auto reenrollment to maintain their health coverage.

Proposing to strip APTC from an enrollee who is eligible for a $0 premium plan, requiring them to return to the exchange to select a plan places an undue burden on them relative to enrollees with somewhat higher income who qualify for less financial assistance. If enrolled unsuspectingly in a plan for the full cost of the premium, or any amount more than $0, the bill will undoubtedly come as a surprise to the patient, and is likely to result in them discontinuing coverage. Furthermore, applying different rules to individuals who have lower incomes than for individuals with relatively higher incomes for the same process could be viewed as discriminatory.

We are also concerned with this proposal as it circumvents established eligibility determination and income verification protocols. The statutory intent described in section 1104 of the ACA was to create an eligibility determination process that posed minimal burden on applicants and enrollees. The auto-renewal system currently in place was designed to avoid documented problems in other means-tested programs that cause people to lose coverage even when they have not experienced any life changes that make them ineligible for assistance. It relies on an intricate process of multiple data matching agreements and incorporates an income verification step, meaning that the enrollee's income level has been verified by the system for the future plan year. If they have been determined eligible for APTC qualifying them for a $0 premium plan, they should not be required to personally reverify and redetermine their eligibility. We encourage CMS to abandon the proposed changes that will unquestionably confuse consumers, increase coverage losses, and interrupt care for low-income individuals.

CSR SEP (§ 155.420)

Enrollees with incomes low enough to qualify for cost-sharing reduction payments (CSR) at the time of their application likely make decisions about which plan to purchase based on their qualification for CSRs. Even if they experience an increase in income during the year that disqualifies them for CSRs, they may not be able to afford the monthly premium for a silver-level plan. People living with HIV, HCV and other chronic conditions must carefully weigh their

[1] CMS Fact Sheet. *Health Insurance Exchanges 2019 Open Enrollment Report*. March 2019. https://www.cms.gov/newsroom/fact-sheets/health-insurance-exchanges-2019-open-enrollment-report

financial obligations related to their treatment, including their premium and deductible payments. We appreciate HHS' recognition of this hardship in its proposal to allow a special enrollment period (SEP) for such individuals along with the option to change plans to a metal-level above or below their existing plan. This will ensure that enrollees are able to find a plan that best fits their health and financial needs. We support this proposal, and urge HHS to finalize it as written.

Cost-Sharing Requirements (§ 156.130)

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 and other chronic health conditions that require high-tiered medications. 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 only just now becoming available for pre-exposure prophylaxis (PrEP) for the prevention of, 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 *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* maintained by the Department of Health and Human Services (HHS) still involve at least one brand-name drug with no generic equivalent, and/or require breaking up single-tablet regimens widely considered critical to medication adherence.[2]

HHCAWG opposes the proposed change to § 156.130(h) to permit insurers to not count support from drug manufacturers toward the annual limitation on cost sharing (a practice commonly referred to as a "copay accumulator" program). Similarly, we do not think that it is proper or consistent with the ACA and other regulations promulgated by HHS to interpret the definition of cost sharing to exclude drug manufacturer coupons. Section 1302(c)(3)(A) of the Affordable Care Act defines cost sharing to include: (1) Deductibles, coinsurance, copayments, or similar charges; and (2) any other expenditure required of an insured individual. Further, regulations define cost sharing as "any expenditure required by or *on behalf of* an enrollee with respect to essential health benefits" (45 CFR § 155.20).

HHS suggests that amounts paid via manufacturer copay assistance should be excluded from the definition of cost sharing because it reduces the patients' financial obligation. This premise is false from the start. Manufacturer assistance does not alter the obligation that an insurer imposes on a patient to pay for their prescription medication, it is simply a way for consumers to fulfill this obligation, similar to income received from a job or a gift from a relative. Any payments made on behalf of an enrollee should count towards cost sharing and the annual limitation on cost sharing. Allowing plans to exclude these amounts effectively authorizes insurers to collect more than the ACA's annual out-of-pocket maximum. In fact, plans/PBMs

[2] HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*. Updated December 18, 2019. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/37/

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)[3], 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.

We urge HHS to reimpose the middle ground approach articulated in the final 2020 Notice of Benefit and Payment Parameters, limiting the use of co-pay accumulator policies to situations where there is a generic equivalent or a patient has gained access to the brand name drug through their insurance plan's exceptions or appeals process. Imposing copay accumulator programs on consumers who have no other choice but an expensive brand-name medication not only does nothing to bring down drug costs, but pose significant individual and public health harms by cutting off access to lifesaving medications.

At minimum, HHS should require clear disclosure of plan policy, not just expect that it will occur. Particularly due to the patient community's reliance on manufacturer copay assistance programs, we are concerned that consumers may expect their drug coupons to count toward their annual limit and not learn of plan rules excluding coupons until after they incur drug costs they thought would be covered. Additionally, we are concerned that HHS' proposed interpretation of cost sharing creates a default of excluding coupons from the annual limitation on cost-sharing such that insurers may adopt this as the prevailing standard for the 2021 benefit year and unduly burden consumers with unexpected financial obligations.

We therefore urge HHS to require issuers and group health plans to provide a clear description of their policy regarding drug manufacturer coupons to all enrollees and prospective enrollees, in all materials that consumers may use to select, plan and understand their benefits. Plans should be required to publish the existence of a copay accumulator policy in their Summary of Benefits and Coverage to promote transparency and ensure that consumers are able to make informed choices about the best plan for them. We note that this language must be explicit and not interfere with other third-party payment obligations for people living with HIV. 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.

HHS Risk Adjustment (§ 153.320)

We appreciate HHS' recognition that pre-exposure prophylaxis (PrEP) should be included in the simulation of plan liability for HHS' adult and child risk adjustment models for the 2021 benefit

[3] NASTAD, *CO-PAY ACCUMULATORS: Considerations for HIV and Hepatitis,* October 2018. https://www.nastad.org/sites/default/files/Uploads/2018/copayaccumulatorfactsheet.pdf

year model recalibration. We understand that, given the structure of HCCs and RXCs, it is not pragmatic to incorporate preventive services such as PrEP into the RXC 1 model as PrEP does not indicate a diagnosis of HIV. While HHS notes that it plans to incorporate PrEP into the recalibration model by "ensuring that 100 percent of the cost" is reflected in the simulation of plan liability, we pause to note the full breadth of these costs.

According to the CDC PrEP Guidelines, there are a number of services in addition to the medication itself that are integral to the PrEP intervention. These services must be covered without cost sharing, and as such should be considered in HHS' risk adjustment calculations. While no specific guidance has been issued to date, existing sub-regulatory guidance on similar USPSTF recommended services have similarly required coverage of ancillary services that are inextricable from the underlying intervention (for example, CCIIO has stated that a polyp removal that occurs in the course of a colonoscopy that meets USPSTF criteria must also be covered without cost sharing as polyp removal is "an integral part of a colonoscopy").[4] At a minimum, the following should be provided without cost sharing when prescribing PrEP, included in the risk adjustment calculations, and regulators should clarify this coverage obligation in supplemental sub-regulatory guidance.

Service	**Interval**
Clinical visit (with a primary care provider, infectious disease specialist, pharmacist, or public health clinic)	At PrEP initiation and every three months
HIV test	At PrEP initiation and every three months
Pregnancy testing of all cisgender women and transgender men with reproductive potential	At PrEP initiation and every three months
Hepatitis B test	At PrEP initiation and every three months
Medication adverse event assessment, adherence counseling, and behavioral risk reduction support	At PrEP initiation and every three months
Bacterial STI tests, including three-site extragenital testing for chlamydia and gonorrhea	Every three months
Renal functioning test	At PrEP initiation and every three months

Annual Reporting of State-Required Benefits (§ 156.111)

HHCAWG opposes the proposal to require states to annually report benefit mandates enacted pursuant to state law. We note that the Center for Consumer Information and Insurance

[4] CCIIO, Affordable Care Act Implementation FAQs – Set 12, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

Oversight already publishes state mandates and their year of enactment on its website.[5] Requiring states to report this information annually only serves to add another burdensome requirement on states with no value in return. Additionally, the proposed rule, if implemented as written, would discourage states from improving coverage using the existing authority under the EHB benchmark selection process.

The ACA requires states to identify and defray the costs for mandates enacted after December 31, 2011. However, HHS provides no evidence showing that states are violating this federal requirement. Rather than promoting state flexibility, this proposal would impose such a burdensome requirement that it will deter states from improving their EHB benchmark plans. Several states are using current authority to update their EHB benchmark plans and expand services in critical areas. Under this proposal, states would need to submit an annual report that: identifies all state-required benefits regardless of whether those benefits are considered part of EHB; provides information explaining why the state believes the mandate is or is not part of EHB; and provides information about any mandate that has been amended or repealed. States will likely be reluctant to improve or expand benefits under the EHB benchmarking process, fearing that such improvements may run afoul of the complex mandate reporting requirements.

These requirements represent a significant departure from the current standard, which requires states to inform HHS of state mandates and their corresponding date of enactment, without additional explanation for why the state believes the mandate triggers or does not trigger defrayal. Adopting these new requirements will effectively transform a workable and simple task into an arduous and complicated endeavor put in place as a solution to an inexistent problem. We urge HHS to withdraw this proposal.

Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

HHCAWG supports the proposal to revise 158.140(b)(1)(i) to require that price concessions received by the issuer, and any prescription drug rebates or other price concessions received and retained by an entity providing pharmacy benefit management services to the issuer that are associated with administering the issuer's prescription drug benefits be deducted from incurred claims for the calculation of Medical Loss Ratio (MLR). We agree with HHS that current regulations do not capture situations in which an issuer allows a pharmacy benefit manager to retain a portion or all of the rebates or price concessions, creating an incentive to engage in these arrangements and pushing the benefit of these rebates away from enrollees. Requiring insurers to count the value of rebates and negotiated discounts for prescription drugs, whether retained by the issuer or by their pharmacy benefit manager, is in line with the purpose of the ACA's MLR provision to ensure that issuers spend the bulk of the income they gain from or on behalf of enrollees on care instead of profits.

[5] See https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb#ehb.

Premium Adjustment Percentage (§ 156.130)

HHCAWG opposed the proposed changes to the premium adjustment calculation and urges HHS to withdraw this proposal. We reiterate our concerns in response to the adjustment to the premium adjustment percentage announced in the Notice of Benefit and Payment Parameters 2020 Final Rule: including Exchange premiums in the calculation of per enrollee premium will raise costs for millions of consumers, including by raising enrollees' out-of-pocket maximums and forcing enrollees to shoulder higher premiums. The previous methodology for calculating the premium adjustment percentage 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. Particularly in light of the recent regulatory changes expanding the availability of 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 withdraw this proposal and reinstate the premium adjustment percentage methodology used in 2019.

Thank you for the opportunity to comment on this proposed rule. Our comments include numerous citations to supporting research, including direct links for HHS' benefit in reviewing our comments. We direct HHS to each of the sources cited and we request that the full text of each source, along with the full text of our comments be considered part of the administrative record in this matter for purposes of the Administrative Procedure Act. Please contact Phil Waters at pwaters@law.harvard.edu with the Center for Health Law and Policy Innovation, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@nastad.org, or Rachel Klein with The AIDS Institute at RKlein@taimail.org if we can be of assistance.

Respectfully submitted by the undersigned organizations:

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 | Bailey House, Inc. | Black AIDS Institute |Center for Health Law and Policy Innovation | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | John Snow, Inc. (JSI) | Georgia AIDS Coalition | GLMA: Health Professionals Advancing LGBTQ Equality | Harm Reduction Coalition | HealthHIV | HIV Medicine Association | Housing Works | Human Rights Campaign | John Snow, Inc. (JSI) | Lambda Legal | 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 Health Solutions of the University of Illinois | Positive Women's Network - USA | San Francisco AIDS

Foundation | SisterLove | Southern AIDS Coalition | The AIDS Institute | Treatment Access Expansion Project |Treatment Action Group | Thrive Alabama | Vivent Health

Cc: Randy Pate
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