HIV Health Care Access Working Group

October 6, 2016

Submitted via the Federal eRulemaking Portal

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9934-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: RIN 0938-AS95: Comments on HHS Notice of Benefits and Payments Parameters for 2018 Proposed Rule

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-related health care and support services. We appreciate the opportunity to provide comments to the Department of Health and Human Services (HHS) on the proposed rule setting forth the payment parameters and provisions for the 2018 Exchanges (the 2018 Notice). [1]

Standards and protections governing the Qualified Health Plans (QHPs) offered on the federally-facilitated and state-run Exchanges must ensure that the care provided through the QHPs works for people living with HIV and other chronic conditions. HHS must clarify, monitor, and enforce protections governing maximum annual limitations on cost sharing, the standardized plan options, the risk adjustment model, network adequacy, essential community providers, and guaranteed renewability of coverage in ways that ensure access to preventive services, care, and treatment for people living with HIV 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.

REDUCED MAXIMUM ANNUAL LIMITATION ON COST SHARING (§156.130)

We note that the proposed 2018 Notice suggests a maximum annual limitation on cost sharing of $7,350 for self-only coverage and of $14,700 for family coverage. These figures represent a 2.8% increase above the 2017 parameters. We welcome these annual cost-sharing limits, as they are an important protection for people living with HIV and other expensive illnesses.

[1] HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 61456 (September 6, 2016).

At the same time, we urge HHS to ensure that cost sharing is affordable throughout the year, for instance, by offering standardized benefit options that utilize copays instead of co-insurance or allowing patients the option to pay cost sharing amounts due to insurers in twelve equal monthly installments. For people living with HIV, access to life-saving medication can consume a very large percentage of their monthly income on plans with high cost sharing. The Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, put forth by an expert medical panel, inform providers that there are currently six treatment regimens recommended for treatment-naïve people living with HIV.[2] These regimens are not interchangeable: physicians choose the most suitable regimen based on the patient's other health conditions, medical history, medication adherence, and other factors. People living with HIV need access to the six recommended treatment regimens.

For many individuals living with HIV, the annual out-of-pocket (OOP) maximum does not provide sufficient protections because of the high cost sharing per month. For example, Humana's 2016 Silver QHPs in Tennessee required 50% co-insurance for all medications in the six recommended treatment regimens. As illustrated in Table 1, this high co-insurance often translates into payments of over $1,000 per month. Some enrollees may find this prohibitive despite the annual OOP maximum, as they cannot afford the initial months of medication and therefore will never spend enough to reach the OOP maximum.

Table 1: Cost Sharing for Recommended HIV Treatment Regimens in Humana 2016 Silver QHPs

Humana 3800 Silver-level QHPs	**Monthly Cost of Regimen (Big 4 Prices)[3]**	**Cost of Regimen (Co-Insurance)**	**Annual Cost of Regimen**
Tenofovir/Emtricitabine (**Truvada**) + Raltegravir (**Isentress**)	$1,112.12	$556.06	$6,672.72

[2] U.S. Dept. of Health & Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC), *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: When to Start: Initial Combination Regimens for the Antiretroviral-Naïve Patient*, AIDSINFO, https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf (last visited Sept. 22, 2016).

[3] The prices negotiated between insurers to pharmaceutical companies for medications are proprietary information and therefore not publicly available. However, there are several public indexes that provide a framework by which drug prices can be determined. The Average Wholesale Price (AWP) index is valuable, but considered an inflated cost estimate, since it does not accommodate for negotiation between parties or any mandated discounts. The Big 4 Price, on the other hand, is the amount paid by four government agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the U.S. Coast Guard—and reflects a mandatory discount and as well as any further negotiated discounts. Because of the mandatory and negotiated discounts, the Big 4 price is likely similar to what insurers pay. Insurers, however, are likely to enjoy even deeper discounts than the Big 4 agencies. In this analysis, we use the Big 4 pricing index to conservatively estimate costs for private insurers.

Tenofovir/Emtricitabine (**Truvada**) + Dolutegravir (**Tivicay**)	$1,712.43	$856.22	$10,274.58
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as **Stribild**)	$2,422.41	$1,211.21	$14,534.46
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as **Genvoya**)	$2,422.34	$1,211.17	$14,534.04
Tenofovir/Emtricitabine (**Truvada**) + Darunavir (**Prezista**) + Ritonavir (**Norvir**)	$1,630.36	$815.27	$9,783.24
Abacavir/Lamivudine + Dolutegravir (co-formulated as **Triumeq**)	$2,184.73	$1,092.37	$13,108.38

Requiring insurers to allow enrollees to make cost sharing payments in twelve equal installments would leave insurers with the same amount of revenue, while making cost sharing more feasible for people living with HIV and other chronic illnesses. For an individual who will eventually hit the annual maximum cost sharing limit of $7,350, the equivalent maximum monthly payment would be $612.50 under a monthly OOP system. We therefore urge HHS to provide an option for patients to pay cost sharing amounts due to insurers in twelve equal monthly installments.[4]

STANDARDIZED OPTIONS (§156.20)

As we did for the 2017 Notice, we applaud HHS for continuing to support Standardized Options (also referred to as the Simple Choice plans). We agree that shopping for insurance coverage can be an overwhelming experience for many consumers, and we support HHS' proposal to simplify this process.

We strongly support the proposal to update the standardized plans, and we commend HHS for creating plans that respond to state-specific cost sharing laws. However, we are deeply concerned that the 2018 Proposed Standardized Options include co-insurance, rather than co-payment, as the cost-sharing option for Specialty drugs across Metal levels and for Preferred and Non-Preferred drugs at the Bronze level. This plan design discourages enrollees from accessing medically necessary drugs, and allowing it as a standardized option reinforces issuer use of co-insurance.

We are particularly concerned that HHS has proposed standardized options that include co-insurance when HHS has simultaneously proposed state-specific standardized options that prohibit co-insurance. The options in Table 13 demonstrate that rational plan design without co-insurance for drugs is readily obtainable, and we emphatically urge HHS to adopt these plan designs as the base standardized option. By requiring standardized options in some states to include co-insurance while prohibiting co-insurance

[4] Some patients who utilize manufacturer co-payment cards may benefit from an annually calculated OOP maximum, so we urge HHS to allow consumers to select the annual or monthly option, as best protects their interests.

in others, HHS establishes a two-tiered Marketplace system. Instead, HHS should establish nationwide standardized plans that comply with all state limitations on cost-sharing. This would be consistent with HHS' proposal to pool risk across states and other risk-adjustment processes, and it will encourage more nationally-standardized plan designs that can be more easily reviewed for discriminatory behavior.

We continue to believe that HHS can improve the proposed standardized options to better serve the HIV and other chronic conditions communities. We caution HHS against designing the standardized options to be as similar as possible to popular pre-existing QHPs because the existing plans offered often do not meet the needs of people living with chronic conditions, including HIV. For example, the Center for Health Law and Policy Innovation (CHLPI), in conjunction with state partners, analyzed the 2016 QHPs available on 18 state Marketplaces for coverage and cost of critical HIV and HCV medications. Because of limited coverage and prohibitively high cost sharing imposed on the federally recommended HIV treatment regimens, CHLPI filed Office for Civil Rights Complaints in eight states against fourteen insurers, including market leaders such as Humana, Cigna, and Anthem Blue Cross Blue Shield.[5] Popularity does not necessarily indicate that the plans selected as models for the proposed standardized options fairly serve the needs of individuals living with chronic conditions such as HIV. This is especially a concern as insurers who do not impose discriminatory cost sharing and poor coverage increasingly find it hard to compete with insurers who do. It is important for HHS to evaluate any plans it selects as a model to avoid incorporating discriminatory plan design into its standardized options.

Specifically, we are concerned at the high levels of cost sharing set for specialty drugs by the proposed 2018 Simple Choice plans. The proposed Silver and Silver 73% CSR plans require 40% co-insurance for specialty medication, which is a significant jump from the next highest tier, which only requires a $100 co-payment. This is a significant concern to the HIV community because, in the majority of Silver 2016 QHPs, the vast majority or all HIV medications were placed in the specialty tier. HIV medications are generally expensive. Requiring enrollees to shoulder 40% of this cost is prohibitively burdensome. Although the Out of Pocket (OOP) Maximum will provide some protection for consumers, with high enough monthly co-insurance many individuals will not be able to afford the first several months of cost sharing and, thus, never reach the OOP maximum. For example, the Big 4 price for Triumeq, a single table regimen recommended by HHS, is $2,184.73 per month. The co-insurance in the bronze and selected Silver Simple Choice Plans would be $873.89, which would be challenging for many consumers to pay.

We urge HHS to reconsider using co-insurance for the specialty tier in its Simple Choice Plans, and to instead use copayments in all its standardized options. Co-insurance often conceals the true out of pocket cost from enrollees and potential enrollees who usually do not know how much a drug costs and, therefore, have difficulty calculating the expected coinsurance. We understand HHS's hesitancy with

[5] To view the 2016 Office for Civil Rights Complaints filed by CHLPI please visit: http://www.chlpi.org/chlpi-publication-document-type/ocr-complaints/. To view a similar Office for Civil Rights Complaint filed against the 2015 Florida QHPs by the AIDS Institute and the National Health Law Program please visit: http://www.healthlaw.org/publications/browse-all-publications/HHS-HIV-Complaint#.V-66fvkrJpg.

setting dollar amounts nationally for certain services. Therefore, we propose that any coinsurance required in the standardized options will at least have a cap. For instance, a standardized option could have a 20% coinsurance with a maximum out of pocket cost of $100 for certain medications. We also urge HHS to require that insurers not tier all medications for a condition on the specialty tier to avoid requiring individuals to shoulder high co-insurance for their medications. Alternatively, as discussed above, we encourage HHS to divide the OOP maximum from a yearly cap to a month cap, to prevent any individual from receiving prohibitively high charges during in the initial months of a plan.

We strongly support HHS's proposal to exempt in the Simple Choice plans most patient cost-sharing for prescription drugs from deductibles. We also applaud HHS for exempting most medications from the deductible in the proposed standardized Silver and Gold plans, and generic medications from the deductibles in the proposed standardized Bronze plans. Unfortunately, HHS has also proposed continuing to subject cost sharing for all medications except generics to the deductible in the standardized Bronze plans and to remove the deductible exemption for specialty tier drugs at the Silver and Silver 73% CSR plans. As mentioned above, virtually all HIV medications are tiered on the specialty level.

It is vitally important that beneficiaries have first dollar coverage for their HIV medications to avoid any unnecessary barriers to care. We urge HHS to continue to exempt specialty tier drugs from the deductible in all Silver Simple Choice Plans and to disregard the proposed separate drug deductible in order to provide first dollar coverage for individuals enrolled in these plans. We also urge HHS to exempt at least specialty tier drugs, but preferably all medications, from the deductible in the Bronze Simple Choice Plans.

We do not object to HHS continuing to allow issuers to offer non-standardized plans; however, HHS should *require* insurers selling plans on federal marketplaces to offer a standardized plan beginning in 2018. The state-based standardized options operate effectively because they require insurers selling on their respective marketplaces to offer a standardized option. This will help insure that all insurers sell at least one plan that is both transparent and affordable. If this rule is not required, some insurers will elect to not provide a standardized option, and thus, defeat the intended purpose to allow apple to apple comparisons of provider networks, cost-sharing, and drug formularies. Additionally, it will allow insurers who offer worse coverage and high cost sharing for treatments needed by higher-cost enrollees than the Simple Choice plans to benefit from offering discriminatory plan design by dissuading higher-cost individuals from picking their plans and make it more difficult for Simple Choice plans to remain financially sound.

PROPOSED UPDATES TO THE RISK ADJUSTMENT MODEL (§153.320)

We welcome the improvements to the HHS risk adjustment model to better reflect partial year enrollment, high-cost risk and prescription drug utilization. The goal of the risk adjustment program is to "minimize the negative effects of adverse selection and help level the playing field between insurance

companies".[6] It does so by transferring revenue from plans with enrollees with higher actuarial risk to plans with enrollees with lower actuarial risk, thereby reducing the incentive for plans to compete for healthy enrollees and to avoid less healthy enrollees. The risk adjustment model is crucial for maintaining coverage for expensive to insure individuals such as people living with HIV because it allows insurers to adequately serve our community despite the higher costs. For the program to function well, the risk adjustment model used to calculate these payments should be as accurate as possible. The proposed updates to the risk adjustment model, most notably the addition of prescription drug data, are likely to improve the performance of the model and to thus ensure that insurers are incentivized to serve our community properly.

Partial Year Enrollees

Specifically, we applaud the proposed calibration of the risk adjustment model to account for increased risk for partial year enrollees and for extremely high-cost enrollees. While the risk adjustment model already assigns a higher risk score for people living with HIV and other chronic conditions, it potentially ignores that increased risk for partial year enrollees living with HIV or another chronic condition who do not have an encounter with a physician that results in a documented diagnosis of the condition.[7] This may help explain HHS's finding that the model currently underestimates the risks associated with partial year enrollees. Similarly, HHS's finding that "even with risk adjustment in place, issuers may retain an incentive to engage in risk selection in order to avoid … very high-cost enrollees" as the model underestimates costs for extremely high-cost enrollees, has troubling implications for people living with HIV or other expensive chronic illnesses. By compensating insurers for extremely high-risk enrollees, HHS will create fairer exchanges for people living with HIV and other chronic illnesses. We therefore welcome the proposed calibration of the model to reflect the additional risks associated with partial year enrollees and extremely high-cost enrollees.

Addition of Prescription Drug Utilization Information

We similarly welcome the proposed 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 the proposal for HHS to routinely evaluate 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. We also support HHS's proposal to use the United States Pharmacopeia (USP) classification rather than the American Hospital Formulary Service Classification, as

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[6] CENTERS FOR MEDICAID AND MEDICARE SERVICES, HHS-OPERATED RISK ADJUSTMENT METHODOLOGY MEETING – DISCUSSION PAPER (Mar. 24, 2016) at 5, available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.

[7] HHS-OPERATED RISK ADJUSTMENT METHODOLOGY MEETING – DISCUSSION PAPER, *supra* note 1, at 35.

the USP classification is more easily accessible to providers and advocates. However, we caution that the USP classification can lag behind the release of new medications, and therefore using only the drugs listed in the USP to create Prescription Drug Categories (RXCs) may omit the newest, most-effective, and perhaps most expensive drugs from the model. Therefore, as part of HHS' ongoing review of the drug diagnosis pairs, we encourage HHS to include new drugs in the appropriate RXCs, regardless of their inclusion on the current USP. Including these drugs will reduce the incentive for issuers to adversely tier and restrict these drugs, helping ensure that the most vulnerable patients have access to the best treatments.

We strongly encourage HHS to require that all drugs included in the risk-adjustment RXCs be included on QHP formularies. Drugs included in the RXCs are so linked to the treatment of a particular diagnosis that their exclusion from formulary indicates that the formulary does not adequately cover the necessary treatment options for a particular diagnosis. Because drug-based risk-adjustment should mitigate the impact of these drug costs to issuers, they should be affirmatively required to include the full panoply of RXC drugs on their formulary to be eligible for drug-based risk-adjustment payments. Otherwise, issuers may continue to push enrollees to cheaper but less effective or tolerable drug choices within an RXC in order to boost their risk-adjustment payments, while simultaneously failing to provide adequate prescription drug coverage. For example, in 2016, 20 percent of QHPs offered on the Federally-Facilitated Exchanges only covered the oldest and least recommended of the four single-tablet regimens available to treat HIV, while 15 percent of plans did not cover any of the six HIV drugs approved since 2013 – clearly demonstrating the need for plans to cover all medications associated with risk-adjustment RXCs.[8]

We do, however, urge HHS to include tenofovir/emtricitabine (Truvada) on the RXC-HCC list related to HIV even for people who do not have HIV. Truvada is the sole drug available as pre-exposure prophylaxis (PrEP) in the United States. PrEP is used by people who do not have HIV to prevent them from contracting HIV/AIDS. PrEP is effective as a preventive measure, according to 2014 Centers for Disease Control clinical practice guideline.[9] The guideline suggests that PrEP be recommended as a preventive measure for people who are at substantial risk of HIV acquisition, including men who have sex with men (MSM) and serodiscordant couples. Given PrEP's effectiveness in preventing HIV and the high medical and public health costs associated with HIV, HHS should encourage plans to cover Truvada so that physicians can prescribe Truvada for people at high risk of HIV acquisition. 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".[10] We believe that including Truvada on the RXC-

[8] NASTAD. Discriminatory Design: HIV Treatment in the Marketplace. July 2016, available at https://www.nastad.org/blog/discriminatory-design-hiv-treatment-marketplace.

[9] U.S. PUBLIC HEALTH SERVICE, PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – A CLINICAL PRACTICE GUIDELINE (2014) at 14, available at https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

[10] HHS-OPERATED RISK ADJUSTMENT METHODOLOGY MEETING – DISCUSSION PAPER, *supra* note 1, at 41.

HCC list for use by people who do not have HIV will encourage insurers to cover it under cost sharing terms feasible for consumers, since insurers will receive credit for it in the risk adjustment model. In the long-term, this preventive approach will result in public health benefits as well as cost savings. Therefore, while we applaud the proposed use of prescription drug data as an input in the risk adjustment model, we urge HHS to include Truvada in the RXC for HIV, even for people who do not have HIV.

High-Cost Risk Pooling

We support the proposal to pool high-cost enrollees across all states where HHS is operating the risk adjustment program. Recent issuer departures from certain markets demonstrate that some states may be more challenging than others for issuers to operate effectively, yet multiple issuers are needed to ensure a robust insurance market. Pooling risk adjustment across states would prevent particular states and issuers from bearing a disproportionate burden of unpredictable risk, fostering a more competitive insurance marketplace.

ENROLLMENT OF QUALIFIED INDIVIDUAL INTO QHPS (§ 155.400)

HHS' concerns about binder payments hindering enrollees' ability to effectuate their enrollment are valid, and we support HHS' proposals to allow for more flexibility in binder payment rules. Specifically, we support the proposal to allow issuer extensions of binder payment deadlines, with the protections that such extensions be implemented in a uniform and nondiscriminatory matter. We further support HHS' extension of all binder payment rules to apply to SBE-FP marketplaces, and we strongly support the proposal to not require a binder payment when a current enrollee enrolls, either actively or passively, in any plan with the same issuer.

SPECIAL ENROLLMENT PERIODS (§ 155.420)

We are concerned that HHS is considering any restrictions on the existing Special Enrollment Periods (SEPs). We believe that reports of abuse of SEPs are overblown and are instead used to pull back on SEP flexibility for those truly in need of such enrollment. We agree that any barriers would be more likely to discourage healthier individuals from using SEPs, heightening concerns of adverse selection and creating a negative feedback loop of SEP restrictions. Moreover, the proposed expansions of the risk-adjustment program should account for unexpected costs from partial year enrollments or less healthy enrollees accessing coverage through SEPs, and the focus should be on these programs, rather than restricting SEPs. We support codifying the SEPs identified through prior guidance, particularly for those individuals who faced errors with enrollment in Medicaid or CHIP, who faced errors in Exchange enrollment, and those affected by data matching issues. We also support codification of SEPs for mixed status Indian families and victims of domestic abuse or spousal abandonment.

NETWORK ADEQUACY STANDARDS (§ 156.230)

While we applaud the establishment of standard metrics for evaluating network adequacy, we are concerned by the comment in the preamble noting that the additional standards are not intended to discourage narrow networks or stifle flexible plan design. In light of the high number of QHPs that already employ narrow networks to reduce costs – we strongly urge CMS to implement a rating system for provider network coverage and capacity to ensure enrollees are aware of the provider coverage available through their health insurance coverage options and to closely monitor access in narrow metrics. This is particularly important for enrollees with HIV and other chronic conditions who rely on access to providers with special expertise and who may require access to a diversity of providers.

We understand that CMS plans to pilot test the network breadth measure in six states. While this is an important first step, we are disappointed that the measure is not being piloted in more states. We hope that the pilot is being conducted among a diversity of states taking into account state network requirements, geography, population size and public health indicators.

Network Breadth Indicators

We believe it is important for the network breadth indicators to differentiate between integrated delivery systems, QHPs with a narrow network breadth, and QHPs with a broad network breadth. The consumer experiences at each type of QHP may be very different. For enrollees with HIV and others with chronic conditions, the quality and capacity of the provider networks is an important consideration in selecting a QHP. In addition, we hope that increased transparency on network and tiering practices will help discourage QHPs from employing discriminatory contracting policies that may exclude or require higher cost sharing for providers who serve higher cost patients, such as people living with HIV or other chronic conditions. As such, we are generally in favor of providing enrollees with as much concrete information regarding network breadth as possible. We are concerned, however, that QHPs with broad network breadth will not be properly differentiated from integrated delivery systems, and lead some individuals who need broad networks to manage their complex conditions to be locked into a delivery system that does not properly serve their needs.

We urge HHS to properly explain the meaning of integrated delivery systems to consumers as well as the limitations of choice these systems may place on individuals. The definition of an integrated delivery system is based on the definition of an alternative essential community provider, which allows for a network comprised of physicians employed through the insurer or through a single contracted medical group. We are concerned that these networks will not be able to adequately address complex medical needs, such as those of people living with HIV, because there may be a limited number of specialists within the contracted group or because that group is otherwise not optimal for delivery of sensitive and appropriate care. For example, a contracted medical group could have some patient service policies or culture that makes it an inappropriate setting for individuals who have stigmatized medical conditions or come from marginalized cultural groups. Additionally, it raises geographic concerns if all the providers are concentrated in a contracted group and, presumably, one or two locations. Therefore, we are concerned that individuals will not understand that an integrated delivery system may not be appropriate for individuals with complex conditions or cultural backgrounds who require flexibility and a

broad network to assemble an appropriate medical team. We believe that HHS should make it clear that broad network breadth may be important for certain enrollees and avoid any implication that an integrated delivery service label is a positive endorsement.

Cost Sharing for Out of Network Providers in In-network Settings

As we stated in our comment on the 2017 Notice, we strongly support the proposal to count cost sharing toward an enrollee's annual cost-sharing limit for out-of-network providers who are providing services within an in-network setting, including any balance billing charges. We do not support allowing insurers to provide notice that potential ancillary provider out-of-network costs do not count towards the in-network annual cost-sharing limit. We believe that costs incurred while enrollees are receiving essential health benefits in an in-network setting should always count to the cost-sharing limit, even if they are administered by an out-of-network ancillary provider. We also believe that 48 hours is not sufficient notice to alert individuals that they will likely incur additional fees because the provider is out-of-network even though their selected hospital or other setting is in-network. Two days is not sufficient time to allow an individual to weigh his or her options and seek an alternative provider, if necessary.

GUARANTEED RENEWABILITY OF COVERAGE (§147.106)

The interaction of QHP coverage and affordability programs with Medicare has been a challenge for many people living with HIV. As such, we welcome HHS's interest in the interaction of guaranteed renewability for QHP coverage with Medicare eligibility. We stress that for individuals with complex and chronic conditions, such as HIV, continuity of care is paramount. We therefore urge HHS to require renewal of coverage as broadly as possible. Coverage should absolutely be required to be renewed in situations where an individual is clearly maintaining a continuity of care, such as in the proposed scenarios in which coverage would renew in (1) a plan under the same contract of insurance; and (2) under a plan that was modified but is considered under the guaranteed renewability provisions to be the same plan but that would require a new contract.

We urge HHS to finalize the proposal to treat all plans transferred to other issuers within a group to rate review requirements. This requirement is necessary to discourage gaming of the Marketplaces and ensure that enrollees are not subject to excessive cost increases. With this protection in place, we support HHS' proposal to allow such transfers without triggering market withdrawal provisions, as the continued presence of numerous issuers within a Marketplace is crucial to Marketplace success. Similarly, we support HHS' proposal to allow issuers to replace an entire portfolio of products without triggering the market withdrawal penalty so long as all new products are subject to appropriate rate review.

PRE-EXISTING CONDITION INSURANCE PLAN (§152.45)

We applaud HHS's continued focus on high-risk individuals in the Marketplaces by calling for information regarding the experiences of Pre-Existing Condition Insurance Plan (PCIP) enrollees in the

2014-2017 QHPs. Many individuals living with HIV, including a large number of AIDS Drug Assistance Program (ADAP) clients are former PCIP enrollees. ADAPs have been tracking client transitions from PCIP to QHPs since January of 2014 and may be an important source of data for HHS.

As discussed above, these individuals are increasingly seeing challenges relating to coverage and cost of needed medications in their QHPs. We urge HHS to consider not only whether this population has maintained QHP coverage, but also to analyze whether the benefits provided by the QHPs, especially in terms of coverage and cost of key medications, matched the benefits formerly provided by PCIP. As people living with HIV are increasingly discovering, it is not enough to have insurance coverage—it is also important to have coverage that does not engage in discriminatory benefit design practices.

ESSENTIAL COMMUNITY PROVIDERS (§156.235)

The Essential Community Provider (ECP) requirements included in the Affordable Care Act are critical to enrollees with HIV and others who rely on the expertise and services available from safety-net providers, such as Ryan White providers. Since QHPs are not required to designate ECPs in their provider networks, it is difficult to conduct a review of the adequacy of ECP participation in QHP networks, particularly for specialty providers, such as Ryan White providers.

While it is appropriate to recognize multiple ECPs at a single site, we urge HHS not to evaluate ECPs solely by the numbers to ensure the unique expertise offered by the different types of ECPs is available. We continue to be concerned that in recognizing multiple providers at an ECP site separately that the breadth of ECP coverage could be limited and create geographic barriers to accessing ECPs. We also continue to urge CMS to develop a stronger ECP standard to ensure that enrollees living with HIV maintain or gain access to providers with HIV expertise. Additionally, we urge CMS to require QHPs to identify Essential Community Providers by provider type within their provider network directories.

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

Successful enrollment efforts for people living with and at risk for HIV have depended on a mix of Patient Navigators, Certified Application Counselors (CACs), other community providers, and agents and brokers. While we recognize the role that agents and brokers play in assisting consumers to enroll in coverage, we do not support the proposal allowing agents and brokers to participate in "enhanced direct enrollment" functions. We believe that redirecting consumers to healthcare.gov to apply for subsidies is the only way to ensure consumers have the information they need to make an informed choice about their coverage. This is particularly true in cases where a consumer may need additional assistance in resolving complex enrollment issues, where Navigators and CACs specializing in low-income programs and subsidy eligibility may be better able to assist.

In either an enhanced direct enrollment option or the existing direct enrollment option for agents and brokers, we strongly support additional safeguards and protections, including: the requirement that agents and brokers display standardized plan options in a way that distinguishes them from other options (and that displays that deviate from healthcare.gov displays be approved by HHS); a requirement to include additional information about APTCs and CSRs on agent and broker websites; requirements that agents and brokers display all plan options in a uniform way to prevent steering consumers into plans with which the agent and broker has a contract or relationship; and implementation of strict privacy and data protection requirements to ensure sensitive consumer information is not compromised. As agents and brokers take on more consumer enrollment functions, we also support the requirement that they offer post-enrollment assistance to resolve any enrollment issues and ensure continuity and maintenance of coverage throughout the year. To monitor potential conflicts-of-interest and to ensure consumers are receiving appropriate enrollment assistance, we support the additional oversight proposals for agents and brokers, including the ability of HHS to suspend the ability of the agent or broker to transmit information as part of the direct enrollment pathway.

THIRD-PARTY PAYMENTS

Finally, we recognize that HHS is collecting information on potential inappropriate plan steering by providers or provider-affiliated organizations of Medicaid and Medicare eligible patients into QHPs. Through federal regulation and guidance, Ryan White Program grantees (and the sub-grantees with which they contract) are permitted to assist eligible individuals with their premium and cost sharing obligations for QHPs. The insurance assistance provided by the Ryan White Program has allowed tens of thousands of Ryan White Program clients living with HIV afford their health insurance coverage. Importantly, federal "payer of last resort" requirements articulated by the HRSA HIV/AIDS Bureau (see Policy Clarification Notice 13-01, available at http://hab.hrsa.gov/manageyourgrant/pinspals/pcn1305premiumcostsharing.pdf) mitigate the risk of inappropriate plan steering by these providers by requiring vigorous pursuit of enrollment in Medicaid and Medicare for eligible clients. ADAP policies and practices – which include eligibility data sharing agreements with state Medicaid programs in most states – involve periodic and consistent screening clients for Medicaid and Medicare eligibility before screening for assistance with QHP premiums and cost sharing. We urge HHS to consider the vital role that the Ryan White Program plays in assisting low-income people living with HIV to afford their insurance as it reviews the role of third-party payments in QHP access.

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Thank you, again, for the opportunity to comment on the 2018 Notice of Benefit and Payment Parameters. We appreciate the commitment HHS has shown to implementing the ACA in ways that ensure that people living with HIV and other chronic and complex conditions have access to high-quality, affordable health care coverage. Please contact Amy Killelea with the National Alliance of State & Territorial AIDS Directors (akillelea@nastad.org), Andrea Weddle with the HIV Medicine Association

(aweddle@hivma.org), or Robert Greenwald with the Treatment Access Expansion Project (rgreenwa@law.harvard.edu) if we can be of assistance.

Respectfully submitted by:

Treatment Access Expansion Project | National Alliance of State and Territorial AIDS Directors | AIDS Action Baltimore | HIV Medicine Association | AIDS Action Committee of MA | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | The AIDS Institute | AIDS Project Los Angeles | AIDS Treatment Data Network | AIDS United | American Academy of HIV Medicine | Association of Nurses in AIDS Care | Community Access National Network | Communities Advocating Emergency AIDS Relief (CAEAR) Coalition | Gay Men's Health Crisis | Georgia AIDS Coalition | Harlem United | Health and Disability Advocates | HealthHIV | HIVictorious, Inc. | HIV Prevention Justice Alliance | Housing Works | Los Angeles LGBT Center | Moveable Feast | National Minority AIDS Council | The National Working Positive Coalition| Project Inform | San Francisco AIDS Foundation | South Carolina Campaign to End AIDS| Treatment Action Group | VillageCare