HIV Health Care Access Working Group

April 21, 2014

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9949-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond

To Whom It May Concern:

The HIV Health Care Access Working Group (HHCAWG) appreciates the opportunity to comment on the proposed regulation with regard to Exchange and insurance market standards for 2015 and beyond. HHCAWG is a coalition of more than 100 national and community-based organizations representing people living with HIV, HIV medical providers, public health professionals, and advocates who are committed to ensuring access to vital HIV-related prevention, care, and treatment services. Standards ensuring that consumers have access to trained Patient Navigators and other assisters, the prescription drugs they need to stay healthy, and a transparent and fair appeals process are all essential to ensuring that insurance coverage works for people living to HIV and other chronic conditions.

To provide meaningful access to care for people living with HIV, we urge HHS to consider the recommendations and comments detailed below.

ENFORCEMENT

While we appreciate the proposed clarifications to §156.800 with regard to enforcement remedies available to HHS to enforce Qualified Health Plan (QHP) standards in federally facilitated Exchanges/Marketplaces, we strongly urge HHS to promulgate regulations defining the protections provided under the non-discrimination provisions described in §1557 of the ACA. Section 1557 greatly expands existing civil rights protections and is unprecedented in the scope of providers, activities, and programs it reaches. It is therefore essential that HHS develop regulatory and sub-regulatory guidance that is provider, activity, and program-specific and that provides the necessary details of what constitutes discriminatory activity. This guidance must include protections to ensure that design of formularies, provider networks, and cost-sharing structures are both transparent to consumers at enrollment and do not discriminate against people living with HIV.

PATIENT NAVIGATOR AND CERTIFIED APPLICATION COUNSELOR STANDARDS

• Non-Discrimination Exception for Population-Focused Assisters

We strongly support the proposed amendment to §155.120 providing an exception to the non-discrimination provisions governing Navigators, Certified Application Counselors (CACs), and other assisters. The amendment ensures that these non-discrimination
provisions do not inadvertently bar population-specific organizations from utilizing ACA outreach and enrollment training and resources. There are hundreds of Ryan White Program grantees (particularly AIDS Service Organizations and case managers) across the country who are engaged in client outreach and education to ensure that people living with and at risk of HIV are appropriately linked to care and insurance coverage. Assistors that have expertise in reaching people living with HIV as well as familiarity with the Ryan White Program have been essential to ensure that people living with HIV understand their insurance options, including which plans they must enroll in to be eligible for Ryan White Program insurance purchasing assistance.

- **Federal Preemption of State Laws that Interfere with Navigator, CAC, and Assister Functions**
  We strongly support proposed provisions specifying circumstances under which state and local laws and policies limiting Navigators, CACs, and other assisters prevent these programs from fulfilling their mission and functions and are preempted by federal law. The circumstances listed – particularly those that require referral to agents or brokers, limit the ability of assisters to discuss plan options, or require onerous state requirements to becoming an assister such as a fee – cause consumer confusion and limit the availability of ACA enrollment assistance. For instance, state laws that prohibit state and county employees from participating in ACA assister programs explicitly thwart the goals of the Patient Navigator, CAC, and other assister programs and should be preempted by federal law. We agree with language included in the preamble, however, acknowledging that states may enact additional consumer protections to the federal floor as long as these protections do not thwart the goals of federal assister programs. We urge HHS to also apply these standards to state-based assister programs.

- **Meaningful Monitoring and Enforcement Standards**
  Finally, we support the addition of meaningful enforcement standards through §155.206(h) – including imposing a corrective action plan followed by civil money penalties – to ensure that Navigators, CACs, and other assisters in Federally Facilitated Exchanges/Marketplaces adhere to the important consumer protection standards regulating these programs. We appreciate the explicit provisions on monitoring and enforcement of the requirement that Navigators, CACs, and other assisters protect health information and confidentiality, which is a significant concern for people living with HIV. We also support the provisions explicitly allowing any entity, individual, or individual’s authorized representative to file a complaint with HHS alleging that a consumer assistance entity has violated consumer protection rules. We urge HHS to require consumer assistance entities to post information about the complaint process to ensure that consumers understand their rights and how to file a complaint.

**ACCESS STANDARDS FOR CLINICALLY RECOMMENDED NON-FORMULARY MEDICATIONS**

For people living with HIV who are at risk for developing drug resistance, it is imperative to have timely access to a range of medications, including new therapeutic agents as they become available. Therefore, we strongly support additional regulations, including requiring a 24-hour expedited exceptions process if requested by the prescribing medical provider and requiring exceptions to request medications at a lower cost sharing tier. We strongly recommend specifying the processes insurers must have in place to be in compliance with §156.122(c)
(requiring issuers to have procedures in place to allow enrollees to request and gain access to clinically appropriate drugs not covered by the plan). We urge HHS to consider the following:

- Treatment interruptions for people living with HIV and other chronic conditions have individual and public health consequences. Therefore, the exceptions process for any non-formulary medication recommended by the prescribing provider should be expedited and should be simple for consumers and providers to navigate. This expedited process is particularly important for the six protected classes of drugs in Medicare Part D, and any appeal involving drugs in those classes (including antiretroviral medications) should have a 24-hour resolution standard. We urge HHS to require plans to allow enrollees and their providers to request an exception to access the medication at a lower cost sharing tier as is required under Medicare Part D.

- Because the standard of HIV care is rapidly evolving, reference to clinical guidelines is particularly important to ensure that coverage decisions (including both the non-formulary medications exceptions process as well as prior authorization decisions) are based on established medically accepted guidelines (see federal guidelines, including for antiretroviral treatment (ART) and prevention and treatment of opportunistic infections at [http://aidsinfo.nih.gov/guidelines](http://aidsinfo.nih.gov/guidelines)). Plan adjudication of these requests should involve both internal as well as external review, and as required CMS should ensure that beneficiaries are made aware of all of their appeals rights if they are unsuccessful during the expedited process. We also urge that as new drugs are made available, plans not be permitted to remove older drugs from their formularies without good reason when adding new drugs to their plans. This is critical for people with HIV and others who have been successfully maintained on a treatment regimen that is effective for them.

- We appreciate CMS’ acknowledgment in the 2015 QHP guidance that transition protections and policies are important to mitigate disruptions in treatment. As contemplated in the guidance, we strongly urge CMS to require plans to adopt a 30-day transition policy for non-formulary medication upon first presentation at the pharmacy. This protection in place for Medicare Part D has been critical to people with HIV and many others. To facilitate a seamless transition and uninterrupted access to care, we urge HHS to require plans to honor a prescription from an out-of-network provider on first presentation and to ensure that plans have mechanisms to accommodate emergency access to prescription drugs for people who are transitioning to new plans and systems of care. Finally, we urge HHS to adopt a similar transition policy, as considered in the 2015 plan guidance, with regard to continuity of providers and require plans to allow beneficiaries to access existing providers for at least 30 days.

While we support a strong exceptions process for non-formulary drugs, we do not believe it supplants the need for stronger regulatory requirements with regard to scope of plan

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1 Procedures and protections that respect clinical recommendations with regard to brand-name as opposed to generic equivalents are also crucial to ensuring treatment adherence. Melanie Thomson, et al., Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons With HIV: Evidence-Based Recommendations From an International Association of Physicians in AIDS Care Panel, Annals of Internal Medicine. 2012 Jun; 156 (11):817-833.
formularies. For instance, lack of coverage for combination HIV therapies continues to be a significant and widespread problem, causing a major barrier to access to appropriate care and treatment for people living with HIV. Relying on exceptions and appeals processes to access HIV therapies recommended in the federal HIV treatment guidelines and most widely prescribed in practice today compromises quality and outcomes and causes avoidable inefficiencies to an already overburdened health care system.

**PREMIUM PAYMENT RULES**

We support the provision in § 156.265(d)(2) requiring QHPs to establish a date by which an enrollee must make a first premium payment to effectuate coverage. During the first open enrollment period, consumers and Ryan White Program third-party insurance purchasing programs experienced confusion with regard to when payments were due because of a lack of transparency on payment deadlines and processes from plans. In some cases, this lack of transparency resulted in cancellations of coverage for failure to timely pay the first premium. We urge HHS to amend the regulation to allow payment of the first premium up to the day before coverage effective date (rather than allowing plans to set payment dates that are earlier than this day). Delays in plan correspondence with consumers with regard to invoicing and information about where to send the first premium payment have contributed to confusion and, in some cases, plan cancellations. We urge HHS to also impose requirements on insurers to timely invoice consumers in order to ensure enrollees are able to meet the deadline for the first premium payment. Timely invoicing is particularly important when a third-party (e.g., Ryan White Programs) is paying a consumer’s premium on his/her behalf.

**SPECIAL ENROLLMENT PERIODS**

We strongly support the proposed amendments to the special enrollment provisions. The added clarity allowing individuals enrolled in non-calendar year individual health insurance policies that end outside of the Marketplace open enrollment to qualify for a special enrollment period (with access to QHP enrollment 60 days prior to ending of coverage) will allow consumers to sign up for QHP coverage without experiencing harmful disruptions in access to insurance. In addition to loss of pregnancy-related Medicaid services, we also urge HHS to designate loss of any limited Medicaid coverage, such as Medically Needy coverage, as a triggering event for a special enrollment period.

**QUALITY AND ENROLLEE SATISFACTION MEASURES**

To ensure that QHPs are providing quality and culturally competent care, HHS must monitor appropriate quality and consumer satisfaction metrics. We support the proposed provisions regarding implementation of both the Quality Rating System (QRS) and Enrollee Satisfaction Survey (ESS). We also support implementation of a Marketplace Survey and urge HHS to include feedback on consumer experiences utilizing Marketplace portals, accessing consumer assistance from call centers, email, and assister entities, accessing appeals processes and information, and applying for special enrollment periods and application extensions.

Because monitoring for effective management of HIV is critical to promote improved individual health outcomes, improve public health, and contain health care costs, in future versions of the QRS, we urge HHS to include HIV-specific performance indicators. At a minimum, the QRS should include an indicator for viral load suppression among patients diagnosed with HIV. The viral load suppression measure (National Qualify Forum [NQF] #2080) is presently the only
nationally endorsed outcome measure for HIV care. In addition, it has been adopted uniformly by the NQF, the Medicare Physician Quality Reporting System (PQRS), the Electronic Health Record Meaningful Use Programs, CMS’s Core Set of Health Quality Measures for Medicaid-Eligible Adults as well as the HHS Secretary’s core HIV measures set. HHS has developed standard core performance indicators for monitoring HIV prevention, treatment, and care and is working to implement these measures across federal payers and programs. Implementation of these measures by private health plans is critical to fully monitor progress in care and delivery across third-party payers.2

**REEVALUATION OF EHB DEFINITION APPROACH IN 2016**

We strongly urge HHS to adopt a new process both for defining EHB and for ensuring meaningful stakeholder involvement at both the state and federal levels for 2016 and beyond. Specifically, we urge HHS to move away from a benchmark model, which enshrines current disparities and geographic variation into the insurance market. Instead, HHS should adopt an approach that sets a higher and clearly defined national standard for benefits coverage that meets the care and treatment needs of people living with HIV and other chronic conditions. We also urge HHS to consider more robust stakeholder engagement in the process used to assess the current EHB approach and whether to adopt a new approach in 2016.

We also urge HHS to reevaluate the EHB benchmark drug counts for 2015. Since state benchmark plans were approved, new and more effective drugs have been introduced, which are not currently included in the posted benchmark plan drug counts. In addition, the United States Pharmacopeia (USP) Medicare Model Guidelines (upon which the drug classification system for the benchmark plan drug counts are based) has been updated to include combination therapies and new viral hepatitis medications. HHS should update the way it measures compliance with the EHB prescription drug requirement to ensure that people living with HIV and other chronic conditions have access to effective medications.

Thank you for the opportunity to offer comments to this proposed rule and for your commitment to implementing the ACA in ways that ensure access to prevention, care, and treatment for people living with HIV and other chronic conditions. 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 the Steering Committee of the HIV Health Care Access Working Group,


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