February 24, 2014

Mr. Gary Cohen
Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
200 Independence Ave, S.W.
Washington, D.C. 20201

RE: Comments on Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Mr. Cohen:

The AIDS Institute is pleased to provide comments to the Center for Consumer Information and Insurance Oversight (CCIIO) on the “Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces.” We remain fully committed to the successful implementation of the Affordable Care Act (ACA) and the opportunities it provides to assist people in accessing quality and affordable health care, regardless of their health condition. We are particularly interested in ensuring the ACA works for people living with HIV/AIDS and hepatitis. The AIDS Institute submits these comments based on the needs of these two patient communities, our extensive involvement in the ACA regulatory process working in coalition with HIV and other chronic disease groups, and our review of the 2014 Quality Health Plans (QHPs), particularly in the state of Florida.

**CMS Must Enforce ACA Anti-discrimination Provisions**

Before addressing the specifics in the “Draft 2015 Issuers Letter,” we would like to reiterate our deep dissatisfaction that CMS has not yet promulgated a regulation or provided guidance on how the critical patient non-discrimination provisions in the ACA are to be enforced. In response to repeated requests by the HIV community and other patients groups, CMS initially indicated it would issue sub-regulatory guidance but then later indicated it will not. Now in a recent communication to the HIV community, CMS wrote that beneficiaries should take concerns to state departments of insurance or call the marketplace call center. This complete disregard for the strict federal anti-discrimination protections found in Section 1557 of the ACA is very troubling, and can potentially undermine the success of the ACA and patients’ ability to access quality and affordable health care.

The ACA provisions barring discrimination are very clear. It prohibits insurers from “employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminat[ing] based on an
individual’s race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions.” It also prohibits insurers offering qualified health plans through the exchanges from “employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.”

Based on our review of all the silver level health plans in the Florida exchange, The AIDS Institute found that several plans in Florida are utilizing discriminatory techniques such as 1) placing every HIV and/or hepatitis drug on its highest tier and requiring patients to pay extraordinarily high co-insurance (e.g. 50 percent); 2) requiring prior authorization for every HIV and/or hepatitis drug; 3) displaying incomplete formularies that only list commonly prescribed medications and leave off all HIV and/or hepatitis drugs. Many of these plans also are requiring substantial deductibles, in some instances a separate one for prescriptions.

Other plans in Florida are not engaging in these practices and are placing HIV and hepatitis drugs on varying tiers, with more affordable co-payments. For example, BlueCross Blue Shield of Florida places most HIV drugs on either Tier 1 or 2 with a maximum co-pay of $25 or $70 depending on the tier and plan. Without enforcement by CMS, we are concerned that plans that are not engaging in discriminatory practices this year will negatively alter their plans for next year and patients will be left with no affordable options. Without enforcement there is nothing from stopping this from happening. That is why The AIDS Institute is urging CMS to enforce the ACA anti-discriminatory provisions.

Attached to these comments is a summary of the concerns The AIDS Institute identified in Florida in its review of Silver plans related to coverage of HIV and hepatitis drugs. We and our colleagues are finding similar examples in states throughout the nation.


What CMS has proposed relative to discriminatory benefit design in the “Draft 2015 Issuers Letter” is completely insufficient. In the draft letter, CMS states that enforcement of EHB discriminatory benefit design “is largely conducted by the states.” Since this guidance is specific to plans sold in states using the federally facilitated marketplace (FFM), we believe CMS should ensure that the benefit design for each plan does not engage in discriminatory behavior. In order to ensure patient protections are met, there needs to be federal review and enforcement. Additionally, many of the states that have federally facilitated exchanges are making no effort to implement the ACA and it is unlikely that these states will take steps to ensure the law is upheld. Even in states that are not federally facilitated, there needs to be a federal mechanism to ensure patients are not discriminated against.

Further, the letter states that CMS “intends to propose in future rulemaking a review of prescription drugs based on clinical appropriateness that states may choose to implement.” While this can be helpful, CMS is not requiring any plan to follow such a rule, but only suggests states may choose to implement it. CMS should require plans to cover medications in accordance with treatment guidelines.
For plans to self-attest that they will not engage in discriminatory benefit design is clearly not sufficient. While CMS indicates it will monitor compliance, including appeals and complaints, again, such actions are insufficient. CMS in their review of each plan should proactively determine if each plan is engaging in discriminatory practices and not rely on past performance or complaints.

CMS indicates that it will also perform outlier analysis of cost sharing and review plans to determine if there is “an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class.” The letter states CMS “encourages states performing plan management functions in an FFM to implement this type of review.” While we appreciate that CMS is attempting to be responsive to our complaints regarding these practices, CMS is not providing any real enforcement mechanism or proposing any penalties for plans that engage in these practices. Additionally, again, CMS is only “encouraging” states to implement plan reviews for these practices.

In order to correct the flagrant instances of discrimination and other violations we have uncovered in Florida and across the country, CMS has to proactively review plans, take measurable enforcement actions, and impose penalties on violating plans. The proposals in the “Draft 2105 Issuers Letter” clearly are insufficient.

**Prescription Drugs**

In our review of plans, it has been extremely difficult to find drug formularies that are easily accessible and easy to use for the beneficiary. Some issuers only display formularies of drugs that are commonly prescribed and refers patients to another site for a more detailed list. One plan did not even mention their formulary provided was not complete. In the “Draft 2015 Issuers Letter” CMS writes it “expects the URL link to an up-to-date formulary where they can view the covered drugs, including tiering and cost sharing, that are specific to a given QHP.” CMS also states that consumers should not have to log on, enter a policy number or navigate the issuers’ website to locate the link. Additionally, if the issuer has multiple formularies, it should be clear to consumers which directory applies to which QHP. These are all excellent suggestions, and should be requirements.

The AIDS Institute urges CMS to require formularies to be organized in two ways, one by drug name in alphabetic order and the other by drug class. We also believe CMS should require plans to enable consumers to type in on-line the names of their drugs to determine which plans cover them and the respective costs. A search that allows users to type in either the generic or brand name, and returns results for both, is most useful. Additionally, since many plans are employing co-insurance rather than co-pays, The AIDS Institute strongly urges CMS to require plans to inform the consumers how much the drug will cost. When a plan indicates a Tier 5 drug comes with a 50 percent co-insurance, the beneficiary has no idea if their cost will be $100 or $1,000. For many HIV and hepatitis drugs, the latter would frequently be norm. In order for beneficiaries to make the right plan selection, they must have access to this information. The Humana drug search tool is an excellent example of a search tool that provides this information.
We also urge CMS to require all plans to accept third-party payments from the Ryan White HIV/AIDS Program to ensure that people with HIV/AIDS can utilize the plans. In two states, issuers have refused to accept Ryan White Program payments despite CMS’ clarification that it is allowed.

For 2014, CCIIO required plans to base their formulary design on US Pharmacopeia Model Guidelines Version 5.0. Since this version does not adequately cover combination therapy, which are the most widely prescribed antiretrovirals today, many plans did not include these drugs on their formularies. For 2105, The AIDS Institute recommends that the Version 6.0 be utilized, which is more current in the list of drugs and does cover all but one combination drug.

**Network Adequacy**

The AIDS Institute is pleased that CMS is proposing to increase the percentage of essential community health providers, including Ryan White HIV/AIDS program providers that each plan has to include in their area networks. However, if the ACA is to work for people with HIV/AIDS and other low-income and medically underserved beneficiaries, we believe all essential community providers should be able to participate in a plan. If this is not possible, we believe the percentage of essential community providers required in a particular area should be at least 50 percent. We are also pleased that CMS is requiring plans to include an URL to access a plan’s network of providers. Just like drug formularies, such lists must be easily usable by beneficiaries.

The AIDS Institute appreciates this opportunity to comment on the “Draft 2105 Issuers Letter.” If the ACA is going to work for people living with HIV/AIDS and others with chronic conditions, we trust CMS will carefully consider the recommendations we have outlined in these comments. Most importantly, we urge you to take the necessary steps to ensure that plans are not engaging in discriminatory measures. The law needs to be enforced.

Should you have any questions or comments, please feel free to contact me at cschmid@theaidsinstitute.org or 202/462-3042.

Thank you very much.

Sincerely,

![Signature]

Carl E. Schmid II  
Deputy Executive Director

Attachment
Key HIV and Hepatitis Concerns with Florida’s Silver Level Qualified Health Plans

High Tiering of HIV and Hepatitis Drugs

- **CoventryOne** places all HIV drugs on Tier 5 (with a 40% co-insurance after a $1,000 Rx deductible) and most require prior authorization.
- **Cigna** places all HIV and hepatitis drugs on Tier 5 (in some plans with a 40% co-insurance after deductible ranging from $0 to $2,750).
- **Humana** places all HIV and hepatitis drugs on Tier 5 (with a 50% co-insurance after a $1,500 Rx deductible).
- **Aetna** places the majority of HIV drugs on Tier 3, which requires a 50% co-insurance.
- **Preferred Medical** places all HIV drugs and all but two hepatitis drugs on a Specialty Tier, which requires 40% co-insurance and it is unclear whether all will require prior authorization.
- **Health First** places 21 of 28 HIV drugs and 10 of 13 hepatitis drugs on Tier 5 requiring a 30% co-insurance, after a prescription deductible, and requires prior authorization for all drugs for these conditions.

This is particularly concerning when noting that while several issuers engage in this practice, other issuers do not and vary tiering or place HIV drugs on more affordable tiers. Therefore this practice is not a market-norm or necessity. Below are examples of plans with more balanced cost-sharing practices:

- **BlueCross** is the Florida issuer with the largest share of plans in the silver market. Plans place most HIV drugs on either Tier 1 or Tier 2, requiring a co-payment of between $10 and $25 for Tier 1 drugs (after a deductible in some cases) and a co-payment of between $40 and $70 for Tier 2 drugs (after a deductible in some cases). Only one drug is on Tier 3 with a generic or alternate form on a lower tier. Tier 3 co-payments range from $70-$100.
- **Ambetter** places most HIV drugs on Tier 1 and Tier 2 and two HIV drugs on Tier 4. Tier 1 co-payments range from $10 to $25 and Tier 2 co-payments range from $50 to $75 (sometimes after meeting a deductible). Tier 4 drug co-insurance ranges from 20% to 30% (after a deductible) with one plan benefit structure using a $250 (after deductible) co-payment.
- **Florida Healthcare Plans (an independent licensee of Blue Cross)** places HIV drugs on Tier 2 and Tier 3, requiring a $10 co-payment for Tier 2 drugs and a $30 co-payment for Tier 3 drugs (after meeting a deductible).
- **Molina** places most drugs on Tiers 1 and 2, with one drug on Tier 3, and two drugs on Tier 4. Tier 1 requires a $20 co-payment and Tier 2 a $55 co-payment. Tiers 3 and 4 require a 30% co-insurance.

ARVs Not included on Plan Formularies

- Many of the plans do not include all single tablet regimens, which are multiple medications combined in one tablet and are commonly prescribed in the treatment of HIV:
  - **Aetna** does not include Complera or Stribild
- **Ambetter** does not include Complera and Stribild
- **Cigna** does not include Stribild
- **HealthFirst** does not include any single tablet regimen drug (Stribild, Complera, and Atripla), a standard in HIV care. Ziagen appears only to be covered as a solution. The drug is typically prescribed as a tablet.
  - Of the 10 carriers, only two (Humana and Aetna) appear to include the newest approved ARV, Tivicay.

**Use of Prior Authorization Techniques**
- **Health First** requires prior authorization for all HIV and hepatitis drugs, including generics.
- **CoventryOne** requires prior authorization for almost all HIV drugs.
- **Aetna** requires prior authorization for Truvada.
- **Ambetter** requires prior authorization for Fuzeon and Epivir (in both the generic and brand form).
- **Molina** requires prior authorization for 5 HIV drugs.
- **Preferred Medical’s** plan documents and formulary are unclear as to whether prior authorization will be required for all HIV drugs.
- Prior authorization is also used extensively with respect to hepatitis treatment across plans.

**Additional Hepatitis Drug Issues**
- **Aetna** places all hepatitis drugs on the 3rd and 4th tier with 50% coinsurance and with many drugs requiring step therapy and/or prior authorization. Tier 4 drugs have a $500 maximum copay for an up to 30 day supply.
- **CoventyOne** places all hepatitis drugs on their 4th or 5th tier with a respective 30% and 40% co-insurance after deductible. In addition, all hepatitis drugs must be obtained through the plan’s specialty pharmacy.
- **BlueCross** does not cover Tyzeka.
- None of the plans reviewed cover Roferon (Interferon alfa-2a, recombinant).

**High Deductibles, Out of pocket limits, and Premiums**
- The in-network medical or combined deductible for plans reviewed ranged from $0 to $5,750, with out-of-network deductibles reaching $12,500.
- In addition to a medical deductible, many issuers also utilize a prescription drug deductible, ranging from $400 to $1,500 for in-network or preferred coverage and from $800 to $2,000 for out-of-network or non-preferred coverage.
- Out-of-pocket maximums ranged in the plans reviewed from a low of $2,250 to a high of the federally allowable cap of $6,350. About two-thirds of plans reviewed have out-of-pocket maximums towards the upper end of this spread.
- Based on rate information from CCIIO, premiums for silver metal QHPs in the state of FL for a 27 year old ranged from a low of $167 to a high of $395 and averaged $261 per month. Premiums for a 50 year old ranged from $285 to $674 and averaged $445 per month. These amounts do not take into account any possible tax credits which would reduce an individual’s premium.

For a detailed analysis of Florida’s silver mental qualified health plans and their treatment of HIV, hepatitis, and opportunistic infection drugs see: [http://www.theaidsinstitute.org/floridaqhpview](http://www.theaidsinstitute.org/floridaqhpview).

If you have any questions about this analysis, please contact Carl Schmid at: cschmid@theaidsinsitute.org or 202-462-3042.