HIV+HEP
POLICY INSTITUTE

January 2, 2024

Dr. Ellen Montz
Deputy Administrator and Director
Center for Consumer Information & Insurance Oversight
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comments on 2025 Draft Letter to Issuers in the Federally-facilitated Exchanges

Dear Dr. Montz:

The **HIV+Hepatitis Policy Institute**, a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, is pleased to offer comments on the 2025 Draft Letter to Issuers in the Federal-facilitated Exchange (2025 Draft Letter). Since we will be commenting on the *Notice of Benefits and Payment Parameters* for 2025 proposed rule, these comments only pertain to issues addressed in the 2025 Draft Letter.

Issuers Must Count Copay Assistance in Most Instances

While we will be discussing this issue in more detail in our comments on the *2025 Notice of Benefits and Payment Parameters* proposed rule, **we urge CMS to add to the 2025 Final Letter a reminder to issuers that copay assistance for prescription drugs must be counted for all but brand name drugs with a generic equivalent.**

Now that the District Court for D.C. has struck down in *HIV and Hepatitis Policy Institute et al. v. HHS et al.* the section of the *2021 Notice of Benefits and Payment Parameters* rule that allowed issuers to decide if copay assistance can count or not, and that same Court has clarified, at the government's request, that the *2020 Notice of Benefits and Payment Parameters* rule is now in effect, issuers must count copay assistance in most instances and not implement copay accumulators.

While we expect CMS to issue guidance in the short term reminding plans that the *2020 NBPP* rule is now in effect and must be followed, CMS should also include this statement in the 2025 Letter to remind issuers since there has been so much confusion over this issue.

CMS Backsliding on Adverse Tiering Reviews

We are pleased that CMS reiterates to payers that they must comply with the essential health benefits non-discrimination requirements that were first included in the *2017 Letter to Issuers.* These requirements state that placing "all or a majority of drugs needed to treat certain chronic medical conditions" on high cost-sharing tiers "might effectively discriminate against, or discourage enrollment." Additionally, the 2025 Draft Letter reminds issuers that the final 2023 Payment Notice "established adverse tiering as a presumptively discriminatory practice when placing all drugs for particular high-cost chronic condition(s) on the highest formulary tier, even when those drugs are costly." Similar to last year, CMS states it will conduct adverse plan reviews of drugs that are used for the treatment of four health conditions: HIV, hepatitis C, multiple sclerosis, and rheumatoid arthritis.

However, the 2025 Draft Letter ignores the fact that the final 2023 Payment Notice also provides other examples of presumptive discrimination. The Notice states that, "adverse tiering, which occurs when an issuer assigns all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier to discourage enrollment by people with those medical conditions, is presumptively discriminatory under § 156.125." **We urge CMS to add to the 2025 Letter a reminder that "all or the majority of drugs" be included in the example as presumptive discrimination.**

Additionally, the 2025 Draft Letter states plans will only be "flagged for possible adverse tiering if all drugs for at least one of the four medical conditions are placed on the highest effective cost-sharing tier." **We strongly recommend that plans be flagged for adverse tiering for not only when *all* drugs are on the highest tier, but *when all or a majority of* drugs to treat a certain condition are on the highest tiers.** It is critical that CMS review and enforce in either of these situations.

The 2025 Draft Letter also makes no mention that the adverse tiering review will examine for sufficient coverage of drugs to treat these conditions. The language included in the 2024 Letter to Issuers stated, "The adverse tiering review will check that QHPs cover sufficient drugs or drug classes prescribed to treat chronic, and high-cost medical conditions at lower cost tiers." **We urge CMS to reiterate in the final 2025 Letter that the prescription drug reviews include the adequacy of the drugs on the formulary to treat specific conditions in accordance with broadly accepted treatment guidelines and be clinically based, as required by ACA essential health benefit regulations.**

CMS and Not All States Enforcing Existing Regulations

CMS indicated they would conduct adverse tiering reviews of the drugs used to treat the same four conditions in the 2024 Letter to Issuers. We would be interested in learning the results of these reviews and what action CMS has taken against insurers to enforce the longstanding prescription drug coverage regulations. Since CMS repeats that they will conduct the reviews again, for the same exact four health conditions, we wonder if these reviews were actually conducted. Sadly, we continue to find plans that violate the patient protection regulations (see below) and remain extremely disappointed by the lack of enforcement.

It has been clear policy since 2016 that it is discriminatory to design formularies by placing a majority of drugs to treat a specific condition on the highest tiers. And yet, CCIIO seems to continue to not enforce it and instead appears to rely on consumer complaints to identify insurers who violate these important patient protections contained in the ACA. Instead of relying on consumers and patient groups to identify violations, CCIIO and state regulators should be conducting proactive reviews of plans as part of the plan approval process.

Since many state regulators do not seem to have sufficient resources and staff to have full knowledge of HIV treatment and prevention medications, they rely on CCIIO's templates and plan review tools in order to conduct these reviews. Some of them are doing an excellent job of ensuring that plan formularies include the necessary treatments in accordance with treatment guidelines, and not instituting excessive prior authorizations nor engaging in adverse tiering. Other states, including those reviewed by CCIIO, are allowing insurers to violate the law.

On top of that, CCIIO and some states merely ask the issuers to correct a violation once it is identified. These repeated violations have real impacts on patient access and medication affordability. This is not proper enforcement. First, CMS is relying on consumer generated complaints. Then CMS politely points out to the insurer the violation and asks them to correct it. Additionally, it seems that insurers are able to come up with excuses on why they are not violating the law and convince regulators that they are in compliance. Even in the 2025 Draft Letter, it states that CMS will merely "flag" for violations when CMS has already made clear that it is presumptive discrimination for putting all or the majority of drugs to treat a specific condition on the highest tier.

Insurers seem to be able to get away with what they can until they are caught. And, even when they are caught, they can continue to violate the law. This is not how patient groups expect the ACA to be implemented. **We urge you to be more proactive and take decisive enforcement action against insurers that violate the law, levy appropriate penalties, and publicize the reviews and actions taken. The plan reviews for adverse tiering and compliance with all other prescription drug formulary requirements must also be for applied to all drugs to treat all medical conditions, not just those for the four conditions identified in the draft *Letter to Issuers*.**

Recent Plan Reviews for HIV Drug Coverage & Complaints Filed

We base the above comments on recent plan reviews the **HIV+Hepatitis Policy Institute** conducted, complaints we have filed, and the resolution, or lack thereof, of these complaints during the past year.

North Carolina Blue Cross/Blue Shield: On December 22, 2022, **HIV+Hepatitis Policy Institute** and the **North Carolina AIDS Action Network** filed a 1557 discrimination complaint with the North Carolina Insurance Department and the HHS Office of Civil Rights, and sent copies to CCIIO. We found that the 2022 and 2023 plan year formularies employed adverse tiering by placing the vast majority of drugs used to treat and prevent HIV, including several generics, on

Tiers 5 and 6. Additionally, all HIV drugs had quantity limits.

After filing the formal complaints, we received an acknowledgment from OCR, informing us that the case would be handled by its Atlanta office. We never received any acknowledgment from the State of North Carolina and only knew they received the complaint through a local press story.

Month after month, we would routinely check the insurer's website to determine if there was any change in their posted drug formulary. Ultimately, in August 2023, we found that the formulary had been changed, and remarkably, not a single HIV drug was left on the highest and most costly drug tiers. Instead of 48 HIV drugs, including many generics, on Tiers 5 and 6, there were now none. As part of the change, the insurer also moved 19 generic HIV drugs that were on Tiers 4, 5, and 6, to Tier 2, which is the proper tier for generics, and removed "quantity limits" that were previously imposed on all HIV medications.

As a result, depending on the plan, patients will be paying more reasonable and affordable costs.

After OCR saw our press release with this change, they did reach out to us to ask if we wanted to take any additional actions. We recommended some actions and notifications the insurer can take and recommended a financial penalty be imposed. We have had no further communication since acknowledgment of receipt of our request.

To date, we have not heard anything from the North Carolina Insurance Department, but in comments to the press they noted that they see that the insurer has taken action and corrected the situation. Again, through comments made to the press, there has been no indication that the state regulator ever did anything, and we can only conclude that the action taken by the insurer was a result of the negative press the insurer received from the reporting of our complaint.

This is not proper enforcement of ACA patient protections. These violations were going on for years and were brought to the attention of the insurer by several outside parties. It should not take filing a complaint and media coverage to correct the situation.

The adverse tiering North Carolina Blue Cross Blue Shield engaged in had real-life consequences for people living with HIV. In some plans Tiers 5 and 6 translate into 50 percent co-insurance, after a deductible of $7,000 for an individual and $14,000 for a family. Moving the drugs to lower tiers resulted in lower and more reasonable copays.

Community Health Choice Texas: On September 26, 2023, **HIV+Hepatitis Policy Institute** filed a complaint with CCIIO against Community Health Choice Texas for substandard and discriminatory HIV medication coverage and plan design. The complaint was filed with CCIIO because it is the entity responsible for reviewing, approving, and regulating ACA plans for the State of Texas.

In our complaint, we included a number of ACA violations that we identified in the insurer's Premier and Select 2023 plans. Both plans have formularies that severely restrict access to antiretroviral HIV treatment medications, with 36 out of 107 HIV drug formulations listed as "not covered" in "Premier" plans and 54 out of 107 not covered in "Select" plans. Many of the covered drugs are generic formulations of medications that are not widely used in the treatment of HIV. In violation of the ACA, these limited formularies do not adequately cover HIV treatment regimens as specified in national treatment guidelines.

Additionally, the "Select" plans do not cover at least three of the four recommended treatments for initial treatment of HIV (these three regimens are available as single-tablet regimens; the fourth is not available as a single-tablet regimen and the formulary is ambiguous as to its coverage). For the "Premier" plans one is covered and two are not, while the other two are available when broken up into separate medications and not as a single-tablet regimen. In order for a plan to be in accordance with the essential health benefits and not be discriminatory, they must meet clinical guidelines. These do not.

The plans also do not cover many of the other recommended HIV drugs. While each plan does include a couple of complete regimens, the medications that are widely prescribed to treat HIV are mostly not covered. Additionally, some of the covered drugs can be used in combination with other drugs and taken together can form a complete regimen, but this requires the patient to take many drugs at different times of the day.

Included on the formulary are drugs that are no longer recommended in the treatment of HIV or discontinued. And, the plans do not cover commonly prescribed single-tablet regimens, which CMS has noted as being potentially discriminatory.

Finally, most of the covered HIV treatment drugs are in a very high-cost tier, including low-cost generic drugs, and therefore engage in adverse tiering. These high tiers require 50 percent co-insurance.

Despite all these allegations, which were all backed up with complete data and analysis, CCIIO responded to our complaint stating that the plans "appear to offer sufficient coverage" and failed to address all of our complaints. Instead of following its own regulations, they ignore them and have given numerous passes to the insurer.

While acknowledging that one of the plans places all HIV single-tablet regimens on the highest tier, they also note that other plans include at least one single-tablet regimen on a low tier. So that means, for these other plans, all but at least one drug are on higher tiers. But CMS regulation does not say anything about requiring at least one drug on a low tier; instead, it says that when all or almost all drugs to treat a certain condition are on the highest tier it can be discriminatory. These plans, therefore, are violating CMS' regulations but CMS isn't even interpreting their own regulation correctly.

In a major disappointment, CMS acknowledges that 2024 will be the first year it will conduct

adverse tiering reviews and "we have been working closely with QHP issuers to come into compliance with this new review and we plan to continue to work with issuers to prevent adverse tiering in the future."

But, as we noted above, the rule against adverse tiering is anything but new and was issued in 2016. We also noted in our complaint that in 2016–seven years ago–a discrimination complaint was filed against Community Health Choice Texas in a formal Section 1557 complaint for placing almost all HIV drugs on the highest cost-sharing tier. Even though CCIIO found a plan that places *all* drugs on the highest tier, and therefore would be "presumptive discrimination," there is no indication that any action against has been or will be taken against Community Health Choice for engaging in discrimination. Nor did they provide an adequate response to our complaint that other Community Health Choice plans engage in adverse tiering by placing *a majority* of the drugs on the highest tier.

While agreeing with us on which specific drug regimens are the recommended treatments for HIV, which include single and multi-tablet regimens, CCIIO's response does not acknowledge that Select Community Health Choice formularies do not cover at least three out of four of them! Nor that Premier plans only cover some, with some of the covered drugs only available in multiple tablet form, instead of single-tablet regimens.

CCIIO states in its response, "We also identified that these plans cover at least seven single tablet regimens, including Atripla, Complera, Delstrigo, Dovato, Juluca, Symfi, and Trizivir." This very limited list of drugs, which omits several frequently prescribed regimens, only refers to the *Premier* plans and CCIIO fails in its response to recognize the much more limited restricted coverage in the *Select* plans, which only cover Atripla, Symfi, and Complera.

In response, CCIIO states that "issuers have the flexibility to determine which drugs to include on their formularies as determined by clinical evidence." But, in providing this response, CMS is ignoring its own regulations that state when developing a formulary all plans must:

> (H) Ensure the issuer's formulary drug list:
> (1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and
> (*2*) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

Additionally, CMS rules state that "a non-discriminatory benefit design that provides EHB is one that is clinically-based."

In our complaint, we point out that even for the medications that are covered, beneficiaries would be required to take multi-tablets, instead of single-tablet regimens. Again, CCIIO is ignoring its own guidance that states:

> CMS also cautions issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer does not cover a single-tablet drug regimen or extended-release product that is customarily prescribed for HIV patients and is just as effective as a multi-tablet regimen, absent an appropriate reason for the exclusion (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, such HIV patients would benefit from such innovative therapeutic options.

CMS does not provide any appropriate reason for the drug exclusions, allowing the insurer not to cover recommended drugs in treatment guidelines, or not using single-tablet regimens except that plans have flexibility. CCIIO seems to be ignoring its own regulations and guidance.

It is way past time for CMS to be implementing the critical patient protections included in the ACA. Placing drugs on the highest tiers and not covering medications in accordance with treatment guidelines sets a bad example for other states and allows insurers across the country to engage in these practices. We are afraid there will now be a race to the bottom. Since there has been little enforcement and no penalties assessed that we are aware of, insurers will now be even more willing to engage in these discriminatory practices.

We note that in our review of Community Health Choice Texas plans for 2024, despite communicating to CCIIO verbally that we believe we witnessed some improvement, in reality there has been no improvement, and they still engage in these discriminatory practices. (At one point a formulary that included some improvements was posted online, but that has been removed.)

As the key regulator of health insurance throughout the United States and given the direct role CCIIO plays in some states, we call on CCIIO to fully review health insurance plans for benefit designs that discriminate against certain individuals, including adverse tiering and inadequate formularies. Further, we urge you to provide the states with the tools needed to ensure necessary compliance, oversight, and enforcement. **And we urge CCIIO to enforce its own regulations and levy appropriate penalties.**

We should also add that while there is no mention in the 2025 Draft Letter that reminds plans to cover preventive services with zero cost-sharing requirements, we also base our above comments regarding the lack of enforcement and the way CCIIO takes corrective actions against issuers on our experience with PrEP coverage issues. While we continue to hear frequently of PrEP users being charged for the drugs and associated services, years after the requirement has been in effect, enforcement has been mixed and issuers continue to get a pass for violating the law.

Thank you for the opportunity to provide these comments. Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org. Thank you very much.

Sincerely,

Carl E. Schmid II
Executive Director

cc: Jeff Wu, Deputy Director for Policy