



CENTER *for* HEALTH LAW
and POLICY INNOVATION
HARVARD LAW SCHOOL

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Sent via electronic mail

Jeff Grant, Acting Deputy Administrator & Director and Deputy Director
Jeff Wu, Acting Principal Deputy Administrator & Deputy Director for Policy
Center for Consumer Information and Insurance Oversight (CCIIO)
Centers for Medicare and Medicaid Services (CMS)
7501 Wisconsin Ave
Bethesda, MD 20814

Re: Ensuring Non-Discriminatory Qualified Health (QHP) Formulary Design

Dear Jeff Grant and Jeff Wu:

We are writing on behalf of the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI). CHLPI advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities. We are excited by the Administration's commitment to strengthening the Affordable Care Act (ACA) and ensuring high-quality health care is accessible to everyone.

Since 2015, CHLPI has conducted extensive analyses of QHP plan design, with a focus on access to affordable care and treatment for people living with HIV. Reflecting on this research, we have identified opportunities where current federal and state QHP review and enforcement mechanisms can be strengthened and issuer compliance with ACA statutory and regulatory non-discrimination requirements can be improved. Given the important role QHPs have in reducing the country's uninsured rate and the American Families Plan's proposal to extend the expansion of advanced premium tax credits, we hope this information is helpful and timely. We appreciate your consideration of this letter and welcome the opportunity to meet and discuss this with you further.

I. Overview of QHP Review Tools and Medication Access Reforms to Better Identify and Prohibit Discriminatory Formulary Design

As you know, a core charge of CCIIO, working in tandem with state insurance regulators, is to enforce section 1311 of the ACA, which prohibits “marketing practices or benefit designs that have the effect of discouraging enrollment in such plan[s] by individuals with significant health needs.” CMS/CCIIO has provided two representative examples of potential discriminatory plan designs that discourage enrollment of high-cost beneficiaries. The first example is when 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.¹ The second example is when issuers place “most or all drugs that treat a specific condition on the highest cost tiers.”²

While these examples of discriminatory plan design are helpful, our research indicates that QHP formulary design continues to consistently exclude necessary HIV medications or place all or most HIV medications on the highest specialty tiers. We suggest the adoption of the following policy reforms to promote the identification and prohibition of discriminatory plan design:

a. Review and update the non-discrimination “clinical appropriateness” formulary review suite (FRS) tool

As you know, the FRS provides important tools for state and federal insurance regulators to identify potential discriminatory formulary designs. The first tool is a formulary outlier analysis, which measures each plan’s formulary against state and national average coverage thresholds. The second tool measures whether each plan provides “clinically appropriate” coverage based on nationally recognized treatment standards. We support CCIIO’s inclusion of nine conditions that are at particular risk for discriminatory plan design (bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis and schizophrenia). We believe slight modifications to this tool could help ensure that inputs are transparent and clinically based.

One modification would be to update the pre-populated recommended drug count thresholds used in the tool. For the HIV/Antiretroviral (ARV) category (see below), the threshold drug counts are so low for certain classes that they do not reflect EHB benchmark drug count standards or the standard of care for HIV treatment.

¹ Center for Consumer Information and Insurance Oversight, 2017 Letter to Issuers in the Federally-facilitated Marketplaces, <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>.

² *Id.*

CMS Clinical Appropriateness Thresholds for PY2022 FRS

Condition	Test Description	Condition Test ID	Threshold Selected
HIV	Coverage of drugs in the Combination Drugs class.	26	4
	Coverage of drugs in the Integrase Strand Transfer Inhibitors class.	27	1
	Coverage of drugs in the Non-Nucleoside Analog Reverse Transcriptase Inhibitors class.	28	1
	Coverage of drugs in the Nucleoside Analog Reverse Transcriptase Inhibitors class.	29	1
	Coverage of drugs in the Nucleotide Analog Reverse Transcriptase Inhibitors class.	30	1
	Coverage of drugs in the Pharmacokinetic Enhancers class.	31	1
	Coverage of drugs in the Protease Inhibitors class.	32	1

For instance, the pre-populated thresholds for six of the seven ARV classes listed is set at one. Because the EHB prescription drug provision requires plans to cover the greater of one drug per category/class or number of drugs per category/class covered in the state’s benchmark plan (whichever is greater), this means in many cases, the pre-populated thresholds are actually lower than the EHB benchmark standard for the state. Moreover, there is limited information available as to the clinical guidelines used to develop this particular standard of “clinical appropriateness” and the baseline list of individual drugs for each category and class. Finally, while the tool allows regulators to see how many drugs are “restricted” or “unrestricted” in each class (defined as requiring prior authorization or step therapy), there is no defined threshold for what proportion of drugs covered with or without restrictions constitute a discriminatory plan design, leaving that decision to state regulators.³

Adapting this tool could make the inputs more transparent (e.g., citations to relevant clinical guidelines) and easier to use (e.g., defaults that suggest a concrete measure of inappropriate utilization management). These changes will allow this important tool to be more effectively used to identify and hold accountable plans with excessive or arbitrary utilization management across high-cost medications.

b. Update existing FRS tools or create new ones to identify “adverse tiering”

The FRS tools are currently not set up to capture adverse tiering, the practice of placing all or most drugs to treat a certain condition on the highest cost-sharing tier.

³ The discretion given to state regulators about how to enforce the ACA’s non-discrimination provisions means that there is incredible variability in how states approach regulation. Indeed, use of the FRS tools at all is voluntary for state regulators. This discretion creates growing disparities across states. See, e.g., Kate A. McManus, MD, et al. [Regional Disparities in Qualified Health Plans’ Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States](#), JAMA Net Open. 2020;3(6) (finding QHP PA requirements for pre-exposure prophylaxis (PrEP) varied considerably by region, pointing to arbitrary, non-clinical use of PA).

Given that specialty tiers often use co-insurance instead of co-payments, coupled with the high cost of many HIV brand-name medications, adverse tiering can place medications out of reach to many consumers, dissuading them from enrolling in certain plans in the first place. A 2015 article published in the *New England Journal of Medicine* analyzed adverse tiering of HIV medications in 12 states using Healthcare.gov. The study found evidence of adverse tiering in 12 of the 48 plans analyzed, finding that enrollees in adverse tiering plans had an average annual cost per drug that *tripled* that of enrollees in plans with no evidence of adverse tiering.⁴ Given the potential harm associated with this practice, we suggest that CCIIO include an adverse tiering tab in its clinical appropriateness tool. This may be the simplest solution given that the nine conditions prioritized in that tool are also the conditions at risk of being subject to adverse tiering. The tab would capture how many drugs in each category and class were placed on the plan's highest cost-sharing tier(s)⁵ and flag plans that placed a certain proportion of drugs used to treat each condition on the highest tiers. CCIIO could set a threshold proportion and allow state regulators to increase the proportion. A threshold standard would help regulators measure formulary design against a concrete and clinically-based standard rather than the outlier analysis included in the current formulary outlier review tool.

c. Strengthen language regarding non-discrimination review in annual Letter to Issuers

CCIIO's annual Letter to Issuers offers an opportunity to strengthen the language included to make clear that adverse tiering is a form of discriminatory plan. Language could include the following:

“Adverse tiering, or the practice of placing all or most of the drugs recommended or used for treating one condition in the highest tier(s) of cost sharing, is a discriminatory practice used to deter individuals with chronic illnesses from enrolling in the plan. Adverse tiering violates the antidiscrimination provisions of the ACA, Section 1557 and Section 1311. CMS will review plan designs to ensure that plans are not engaged in adverse tiering.”

d. Prohibit plans from listing drugs that are only available through an exceptions process as covered drugs in their QHP submission documents

We believe that CCIIO should include language in QHP certification documents and training material that explicitly prohibits plans from listing drugs only available through a plan exceptions process as part of their formulary. Medications not listed on a publicly available formulary and not available through the plan's regular process

⁴ Jacobs, Douglas B. and Benjamin D. Sommers, [*Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*](#), 372 N Engl J Med. 399, 399–402 (2015).

⁵ In assessing whether all or most drugs are subject to a plan's highest cost-sharing threshold, it is important to note that sometimes the highest cost-sharing will occur across two cost-sharing tiers (e.g., if a plan requires the same cost sharing for HIV drugs in the highest two cost-sharing tiers).

should not be considered part of a plan’s formulary and should not be counted for the purposes of meeting the EHB drug count standard or the clinical appropriateness review.

e. Update the drug classification list used to measure the Essential Health Benefits (EHB) benchmark drug count standards

Based on our research, we think that CCIIO should consider using USP’s Drug Classification (DC) instead of USP’s Medicare Model Guidelines (MMG) to develop the categories and classes of drugs used to determine EHB benchmark compliance as well as to monitor discriminatory plan designs. USP MMG was developed in 2004 through a Cooperative Agreement between USP and CMS in response to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).⁶ In 2013, when HHS selected USP’s Model Guidelines as the standard for EHB requirements, USP DC did not yet exist. USP DC was developed in 2016, and the first version published in 2017.⁷ Though structurally similar to USP MMG, USP DC has more common outpatient drugs, rather than just Part D eligible drugs, and its public comment draws more input from relevant stakeholders from the private health care sector. Most importantly, USP DC is updated annually, while USP MMG is updated once every three years, rendering USP DC more likely to reflect up-to-date information about preferred drugs, discontinued drugs, and drugs no longer used for particular purposes. Alternatively, USP MMG could be updated annually.

II. Issues to Consider in Future Rulemaking

Substantive changes to CCIIO’s annual Notice of Benefit and Payment Parameters Rule could strengthen non-discrimination standards and improve federal monitoring and oversight of formulary design. We believe that the following regulatory changes could help:

- Prohibit mid-year formulary changes that remove medications during a plan year.
- Include a non-exclusive representative list of discriminatory plan designs that are prohibited under 45 CFR § 156.125 and 45 CFR § 156.200 that includes adverse tiering, failure to provide access to treatment regimens that meet clinical standard of care for nine designated conditions, misleading or incomplete formularies, and arbitrary or excessive utilization management.
- Amend the prescription drug exceptions process described in 45 CFR § 156.122 to allow beneficiaries to request a tiering exception if the drug they need is on a high cost-sharing tier.
- Define “specialty medication” and “specialty pharmacy” in 45 CFR 156.122. Without a definition, issuers and PBMs are skirting the requirement that consumers be able to pick up their medications at brick and mortar, in-network retail pharmacies

⁶ Medicare Model Guidelines, USP.org, <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines>.

⁷ Press release, USP, *New USP Drug Classification System Proposed – Comment Now* (Oct. 31, 2016), <https://qualitymatters.usp.org/comment-usp-drug-classification-system>.

by arbitrarily designating certain medications as “specialty” and needing “special handling” that cannot be provided by a retail pharmacy. For instance, HIV and hepatitis C medications are being reclassified by issuers and/or PBMs as needing special handling, despite these medications being distributed by retail pharmacies for years with no issues.

- Bolster federal enforcement of non-discrimination standards by requiring states to conduct meaningful reviews using approved federal templates and by substituting federal review for states that fail to meet these standards.
- Standardize plan choices so that consumers have access to plans that utilize co-payments instead of co-insurance.

Thank you for the work you are doing to protect individuals living with chronic illnesses from discrimination and to ensure these communities have access to comprehensive and affordable health care. We remain hopeful that these reforms could provide meaningful progress for disinvested communities. We would very much appreciate the chance to meet with you to discuss the above suggestions. Please let us know your preference for a Zoom meeting. In the meantime, if we can be of any assistance or provide any other information, please email us at rgreenwa@law.harvard.edu and mtomazic@law.harvard.edu.

Best,



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