CENTER for HEALTH LAW and POLICY INNOVATION
HARVARD LAW SCHOOL

January 31, 2023

Submitted via Regulations.gov

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–9898–NC
P.O. Box 8016
Baltimore, MD 21244–8016

Re: RIN 0938-AV14 "Request for Information; Essential Health Benefits"

Dear Director Chiquita Brooks-LaSure,

This comment is submitted on behalf of the Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School, regarding RIN 0938-AV14 "Request for Information; Essential Health Benefits" (file code: CMS-9898-NC). CHLPI advocates for legal, regulatory, and policy reforms in health and food systems, with a focus on the health, public health, and food needs of systemically marginalized individuals. CHLPI's broad range of initiatives aim to expand access to high-quality health care and nutritious, affordable food; to reduce health- and food-related disparities; to develop community advocacy capacity; and, to promote more equitable, sustainable, and effective health care and food systems.

Since the Affordable Care Act (ACA) was passed, CHLPI has monitored and evaluated access to key prescription drugs, treatments, and services in plans sold on the Marketplace. We have identified areas where Qualified Health Plan (QHP) coverage has been inadequate, unclear, and noncompliant with federal standards. Today, we submit the following comments in support of stronger, more robust Essential Health Benefit (EHB) standards so that people living with HIV, HCV, and other chronic conditions can benefit from the promises of the Affordable Care Act.

I. Benefit Descriptions in EHB-Benchmark Plan Documents

We urge CMS to clarify and strengthen its enforcement of EHB-related standards when the benchmark plan or benchmark plan options available to a state contain discriminatory exclusions of gender-affirming care. Services used to treat gender dysphoria fall within the essential health benefit categories and are associated with certain consumer protections.[1] However, many of the

[1] A state's benchmark plan must have a scope of benefits that addresses the needs of "diverse segments of the population, including women, children, persons with disabilities, and other groups". 45 C.F.R. § 156.111(b)(2). The benchmark plan (and issuers providing EHBs) may not discriminate on present or predicted disability or other health conditions, among other bases. *Id*.; 45 C.F.R. § 156.125. Issuers that provide EHBs are not permitted to discriminate on the basis of race, color, national origin, disability, age, or sex. 45 C.F.R. § 156.125(b). *See also* 45 C.F.R. §

benchmark plans and benchmark plan options available to states include explicit and/or potentially discriminatory exclusions in them.[2] These exclusions are submitted to HHS for review.[3]

Such violations exist not only in benchmark plans and benchmark plan options, but also in plans certified by CMS to be sold in the 2023 federal Health Insurance Marketplace. Out2Enroll's annual analysis reports that "[s]everal insurers—U.S. Health and Life in Kansas and Tennessee, Cox Health Systems and WellFirst Health in Missouri, CommunityCare of Oklahoma, Community First Health Plans and Sendero Health Plans in Texas, and UnitedHealthCare in its plans in 13 states—[] have discriminatory transgender-specific exclusions. The language of these exclusions varied, but all were categorical exclusions of treatment for gender dysphoria, including, for instance, hormone therapy, mental health services, and surgical procedures." Permitting such plans to include discriminatory exclusions for services considered EHBs sends a message that the Administration is not serious about the enforcement of nondiscrimination protections.

II. Barriers of Accessing Services Due to Coverage or Cost

a. Adverse Tiering

Plans that provide EHBs continue to present challenges to consumers who need access to robust prescription drug coverage. Meeting the current regulatory minimum number of drugs per class and category is not sufficient. CMS must ensure, through regulations, guidance, and enforcement, that QHPs available through federal and state Marketplaces offer meaningful coverage to people living with chronic illnesses and do not discriminate based on disability or other health conditions.

For example, while CMS has clarified expectations around nondiscrimination protections in the Notice of Benefit and Payment Parameters for 2023, many states have approved QHPs that engage in adverse tiering and place most or all covered drugs used to treat a certain chronic condition on the most expensive formulary tier and/or subject all covered drugs to burdensome administrative requirements.[4] Examples include:

- In Massachusetts, a review of WellSense's formulary for coverage of Anti-hepatitis C Agents shows that all covered first-line Direct-acting Antivirals (DAAs) (including two

156.200(e) ("A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex."); 45 C.F.R. § 156.1230(b)(2) (requiring QHP issuers that directly enroll applicants in a manner considered through Federally-facilitated Exchanges to refrain from conduct that "discriminates based on race, color, national origin, disability, age, or sex.").

[2] *See e.g.*, Kentucky (excluding coverage of "[s]ex transformation operations and related services"), Louisiana (excluding coverage of "treatment related to sex transformation, sexual function, sexual dysfunctions or inadequacies"), and Oklahoma (excluding coverage of "[f]or transsexual [s]urgery or any treatment leading to or in connection with transsexual [s]urgery"). Benchmark plan information was obtained from http://bit.ly/3RlZ741. *See also*, *Kadel v. Folwell* 446 F.Supp.3d 1, 18 (M.D.N.C. 2020) (discussing state plan exclusion that barred "treatment in conjunction with proposed gender transformation" and "sex changes or modifications"). In *Kadel*, the state defendants "attempt[ed] to frame the exclusion as one focused on 'medical diagnoses, not . . . gender," but the district court rejected this argument, noting that "the diagnosis at issue—gender dysphoria—only results from a discrepancy between assigned sex and gender identity." *Id.*

[3] 45 C.F.R. § 156.120(b)(2)(iv).

[4] HHS Notice of Benefit and Payment Parameters for 2023, 87 Fed. Reg. 27,208, 27,304-5 (May 6, 2022).

generics) are listed on the highest tier, are subject to specialty drug requirements, and are subject to prior authorization requirements.[5]

- In Illinois, a review of Quartz's formulary for coverage of Anti-hepatitis C Agents showed that all covered first-line DAAs are covered on the highest tier, are subject to specialty drug requirements, and are subject to prior authorization requirements.[6]

Federal regulations indicate that "[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's . . . disability, . . . or other health conditions."[7] Discriminatory coverage of an EHB category can lead to overt consumer harm when individuals living with specific chronic conditions are unable to obtain any key medications in an affordable and accessible manner. We urge CMS to publicly work with states and review federal Marketplace plans to ensure that QHPs are not inappropriately certified as providing coverage of EHBs when they do so in violation of nondiscrimination standards.[8]

b. Non-essential Health Benefits

Many self-insured employer plans have also implemented policies that attempt to sidestep the Affordable Care Act's coverage rules for essential health benefits, to the detriment of consumers, by excluding from traditional coverage some or all specialty drugs and deeming them 'non-essential health benefits.'[9] CMS's explicit statement in the RFI that when plans subject to EHB requirements "exceed the minimum number of drugs required to be covered," the "additional drugs would still be considered EHBs" is a welcome step toward combatting these harmful policies.[10] However, the increase in plans that use this "non-essential health benefits" language indicates that more explicit guidance (for example, in the form of an FAQ) and enforcement is necessary.

Plans that employ these policies tell members that affected specialty drugs are subject to a substantial coinsurance if the members do not participate in a copay maximizer or similar program, and that this cost-sharing will not count towards the members' deductibles or out-of-pocket maximums.[11] In these programs, a plan member receives zero or limited coverage of these drugs unless the member applies to copay assistance programs (typically offered by drug manufacturers, charitable foundations, and patient advocacy groups). Co-pay maximizers and other programs then

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[5] Wellsense, CONNECTORCARE AND QHP FORMULARY GUIDEBOOK (Effective as of Jan. 1, 2023), https://perma.cc/2J9S-J27Y.

[6] Quartz, 2023 STANDARD CHOICE DRUG FORMULARY (Jan. 3, 2023), https://perma.cc/993M-B58B.

[7] 45 CFR § 156.125.

[8] Additionally, we urge CMS to work with HHS' Office of Civil Rights, which has received multiple complaints about QHPs that have or continue to provide discriminatory prescription drug coverage. *See, e.g.*, Press Release, Center for Health Law and Policy Innovation, *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living with HIV in Seven States* (Sept. 6, 2016), https://perma.cc/CP8U-GB4U; Press Release, HIV+HEP Policy Institute, *HIV Organizations File Discrimination Complaints Against North Carolina Blue Cross Blue Shield* (Dec. 8, 2022), https://perma.cc/3LJ8-8LYX.

[9] *E.g.*, Albuquerque Public Schools, EXPRESS SCRIPTS SUMMARY OF BENEFITS 2 ("Specialty medications are not one of the ten Essential Health Benefits under the Affordable Care Act (ACA) and are therefore considered non-essential health benefits."), https://perma.cc/Z99Y-5H7M.

[10] Request for Information; Essential Health Benefits, 87 Fed. Reg. 74,097, 74,100 (Dec. 2, 2022).

[11] *E.g.*, *supra* note 9 ("APS members who qualify for, but decline, to sign up with the SaveonSP program will pay the prescription drug copayment amount stated on the SaveonSP program drug list") ("As non-essential health benefits, the cost of specialty drugs that are part of the SaveonSP program will not apply towards satisfying the member's out-of-pocket maximum on the prescription drug plan, nor will they apply towards the out-of-pocket maximum on the member's medical plan.").

alter the monthly cost of the drug to match the maximum assistance the member can get from the copay assistance program.[12]

In other scenarios (such as alternate funding programs), plans will outright **exclude** coverage of certain specialty medications and refer members to an entity, such as the "Mandatory Specialty Drug Advocacy Program", that offers "financial advocacy services to find and qualify alternate partial and full funding sources".[13] If a member chooses not to engage with this program, the drug remains excluded from coverage and the member must pay 100% of the drug's cost. If a member engages with the program and is unable to get alternate funding, the plan will then consider whether to cover the drug under its normal cost-sharing structure. For example, one plan provides:

> "If you need a drug on the Plan's Select Drugs and Products List, you will be required to engage with PaydHealth and an alternative funding entity as may apply for the specific drug or product (respond, provide information, follow-up documentation and seek provider cooperation if requested by the alternative funding entity). If you do not engage and complete the process with a PaydHealth case coordinator, you will not have funding for those specific drugs under the City's prescription drug program and will be responsible for the full cost of those drugs. Should a member be denied alternate funding for any reason (even though you have engaged and completed the required process for the specific drug or product on the Select Drugs and Products Program), your claim will be automatically submitted for benefit reconsideration and coverage under the Plan through MedImpact and become subject to the copay/coinsurance/deductibles described in the Drugs and Medicines section of the Schedule of Medical/Prescription Drug Benefits."[14]

This type of program and strategy is particularly dangerous to consumers and to the future of essential health benefits. The plan outright excludes certain drugs used by many people living with chronic illness and disabilities. Any coverage is contingent on the individual seeking out their own funding outside of the plan. If, and only if, the plan knows the member tried to obtain outside funding, will it then consider covering the drug. This scheme erodes the essential health benefits framework and the spirit of the ACA by allowing plans to provide second-class coverage and significant hurdles for people living with chronic illness and disabilities.[15]

Moreover, even if many consumers in such plans ultimately obtain coverage of their drugs through these and similar programs, obstacles still exist:

> **Administrative Burden**: The administrative process of applying to copay maximizer or other programs is time-consuming ("this is not an overnight solution . . . [it] usually takes

[12] *Id*. ("Copayments for the select group of specialty medications that fall under the SaveonSP program may be set to . . . the amount of any available manufacturer-funded copay assistance amount.")
[13] Mesa, Arizona, PLAN DOCUMENT SUMMARY PLAN DESCRIPTION 33, (Amended, Restated, and Effective January 1, 2023), https://perma.cc/M9EK-V49X.
[14] *Id*. at 13 (emphasis removed).
[15] Consider if such a scheme applied to other essential health benefit categories like lab services or pregnancy care. Insurer A refuses to cover certain HIV lab testing or fetal imaging services and instead refers members to an "advocacy program" that would direct members to specific providers or clinics to seek out care as uninsured/underinsured. If the member refuses, they will receive no coverage of the service. If, and only if, the plan has proof that the member went to their local federally qualified health center or clinic and was ineligible for sliding fee scales, will the plan then cover the needed service.

from two to four weeks on average"[16]) and confusing ("'[D]o you contract with a maximizer?' 'I don't know,' the customer service representative admitted."[17]). And, while the programs are often presented to consumers as being easy to enroll in and efficient, the purpose of the programs along with their requirements and consequences are often unknown. For example, in a Washington Post article, Annabelle Gurwitch describes encountering SaveonSP while undergoing treatment for stage 4 lung cancer: "After I discovered that [$4,445] deduction from my account, I spent the majority of my waking hours that week ping-ponging between customer service representatives of my insurer, Express Scripts and Accredo. (The name SaveOnSP appeared neither on my invoice nor on my account portals at Express Scripts and Accredo.)"[18] Some programs may provide a potential fail safe ("you may be eligible for a short supply of your urgent medications"[19]) but this is far from a promise that coverage will be provided should the plan's administrative burdens cause delay.

Changes in Plan Coverage: Changes in plan coverage, due to a change in employer for example, can present a barrier to certain individuals. Not only do consumers have to restart the administrative process of enrolling into the new plan's copay maximizer or other program ("Each time we change insurances, I hold my breath."[20]), but concerns can arise if the first plan has extracted the majority or all of the person's eligible amount from a copay assistance program. Copay maximizers and similar programs will shift the cost sharing associated with a particular drug to match the financial assistance a person can get from a copay assistance program, even if a person may not be in that plan for the entire year. In Annabelle Gurwitch's case, SaveOnSP had taken the entire allotment of her copay assistance funds in six months, leaving her unsure what to do when she needed to change plans. A similar experience was shared in a comment responding to the Federal Trade Commission's recent Request for Information:

> "Were I still an employee at company A that agreed to SaveOnSP, the Express Scripts/SaveOnSP agreement presumably would have required they ensure my continued 'no cost' coverage despite them maxing out my manufacturer copay assistance program benefits. Instead, I now have prescription benefits through company B. Company B has not implemented this type of maximizer program but does still have significant cost sharing for specialty medications . . . . Were my annual benefits not prematurely capped due to company A's use of SaveOnSP, I would have additional manufacturer program benefits to help with this coinsurance."[21]

Thus, a program designed to extract the maximum financial assistance a consumer can receive from third party programs can leave that consumer—the person intended to benefit

[16] Sharx, INTRODUCING THE SHARX PROGRAM, https://perma.cc/M64C-ZD7A.
[17] Annabelle Gurwitch, *Tackling Cancer While Battling the Insurance System*, WASHINGTON POST, Sept. 9, 2022, https://perma.cc/K69P-59SY.
[18] *Id*.
[19] *Supra* note 16 at 2.
[20] Gurwitch, *supra* note 17 (quoting another lung cancer patient).
[21] Anonymous, Comment Letter on the Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers (May 31, 2022), http://bit.ly/3DnjcBi.

from a manufacturer copay assistance program or non-profit foundation—with no financial support remaining should they need to leave their current plan.

Impact on People Living with Chronic Illness and Disabilities: Copay maximizer and similar programs often target specialty drugs that treat specific chronic illnesses.[22] This practice ensures that people already subject to administrative barriers or who experience negative health outcomes as result of their chronic illness or disability must shoulder extra burdens that other individuals in the same plan do not face. This impact can be inescapable when the individual has no other alternative medication to turn to or when all appropriate medications are reported to be within the copay maximizer or similar programs. Advocates have voiced concerns that these practices are discriminatory, particularly when plans specifically exclude most or all of an entire category of medication used to treat a specific condition. For example, the City of Smyrna, Georgia's 2022 Benefits Overview states that "Specialty Drugs are not covered by the plan" and that members are "responsible for 100% of the cost, which doesn't go towards the out-of-pocket maximum."[23] The Overview further provides examples of specialty drugs, including "HIV medications."[24] A plan that excludes HIV medications from its prescription drug coverage uses a benefit design that ensures people living with HIV are not able to easily access the care they need nor the level of care that others receive from the plan.

Additionally, in response to CMS' request for information about other strategies that plans have implemented to control costs, we wish to highlight the dangerous implications of requiring individuals to obtain medications only through mail order pharmacies. Requirements to obtain certain medications through mail order pharmacies only have long been documented to have negative impacts on people living with chronic illness and disabilities. While mail order may be convenient to some, many people are unable to receive mail-ordered prescriptions safely or privately, compromising the integrity of the drugs and increasing the stigma for recipients.[25] Additionally, mail order programs have a history of untimely and unsafe delivery. For example, Elvin Weir was battling a quick-spreading colorectal cancer, but still faced a two-week delay while his mail-order pharmacy mailed him chemotherapy pills – pills that were already available at a local cancer treatment facility's pharmacy, but not accessible due to mail-order requirements.[26] In another example, Heidi Romero needed a particular medication to ensure a stable pregnancy but was required to obtain it through the mail from a specialty pharmacy:

> "The doctor issued the order for the medication to the specialty pharmacy and the process for obtaining it was so complicated that I had to call multiple times a week to check on the

[22] *E.g.*, PrudentRx, COMPREHENSIVE SPECIALTY DRUG LIST (June 2020), https://perma.cc/Q4PC-KUG5.
[23] City of Smyrna, Georgia, 2023 EMPLOYEE BENEFITS GUIDE 8-9 (accessed Jan. 30, 2023), https://perma.cc/BP5V-3WD5.
[24] *Id.*
[25] For example, NBC News logged temperatures of test bubble mailers sent through the mail and found that temperatures easily reached above 104°F or below 32°F, sometimes for hours. Adiel Kaplan et al., *Millions of Americans receive drugs by mail. But are they safe?,* NBC, Dec. 8, 2020, https://perma.cc/Y2ZV-ALEL. See also Press Release, American Society of Health-System Pharmacies, *Mail-order Medications Often Exposed to Unsafe Temperatures, Study Shows* (Dec. 9, 2020), https:// perma.cc/2TLJ-HHKH (describing a study that found test shipments with temperature data loggers were subject to temperatures outside of the 68-77°F range 68-87% of the delivery time in the winter and 27-54% of the delivery time in the summer).
[26] Marty Schladen & Catherine Candisky, *'Pharmacy benefit manager' system keeps meds from cancer patients*, THE COLUMBUS DISPATCH, June 3, 2018, https://perma.cc/6QHY-P8K4.

> medication status for 4 weeks until it was nearly past the time that I needed to begin the medication. . . . If they had delayed any longer in shipping the medication I would have been past the window of administration and may have lost the pregnancy."[27]

Mail order requirements can also disrupt coordination of pharmacy care as specialty drugs are often carved out of a person's typical patient-pharmacy relationship. In fact, to reduce risks associated with polypharmacy ("the prescription of medications for multiple underlying disease states, or . . . a threshold number of active prescriptions—such as the concurrent administration of 5 or more medications"[28]), the National Coordinating Council for Medication Error Reporting and Prevention recommends patients consider having a single "pharmacy home" where "[their] pharmacist has access to [their] complete medication history and current regimen."[29] Similar coordination of care issues arise in copay maximizer and similar programs as specialty drugs included in those programs are typically mailed from the program's contracted pharmacy.

III. Changes in Medical Evidence and Scientific Advancement

We are pleased to see CMS' consideration of whether EHB requirements can better address nutrition-related health conditions consistent with the Department's commitments in the Biden-Harris National Strategy on Hunger, Nutrition and Health. Food is Medicine research to date overwhelmingly demonstrates the effectiveness of nutrition interventions such as medically tailored meals, medically tailored groceries, and produce prescriptions.[30]

The proliferation of policy-promoted nutrition interventions in Medicaid (through, for example, the in lieu of services flexibility) and in Medicare (through, for example, Special Supplemental Benefits for the Chronically Ill) highlight the potential value of a similar approach in the private insurance market. Moreover, we are aware of states that include and/or are exploring some form of coverage of nutrition-related care via EHB. For example, several states now include nutritional counseling for one or more diet-related conditions. At least one state, Vermont, has been exploring the inclusion of a medically tailored meal benefit as an EHB. A federal standard would propel adoption and ensure more equitable access to (at least a baseline) of nutrition-related services across the country.

Finally, we note that recent policy changes create or otherwise promote the necessary enabling infrastructure for successful nutrition-related EHBs. Plans and providers are increasingly adopting food insecurity screenings, at least in their public insurance markets, due to additional quality standards and requirements to conduct screenings for health-related social needs as part of regular health risk assessments. 2022 rulemaking surrounding EHB nondiscrimination provisions clarifies that a nutrition benefit may be offered only in connection with certain conditions as long as the

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[27] Heidi Romero, Comment Letter on the Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers (May 31, 2022), http://bit.ly/3RprWNe.
[28] HIVPractice, Polypharmacy and HIV, https://perma.cc/ R9Z4-HJE9 (footnote omitted).
[29] Nat'l Coordinating Council for Med. Error Reporting & Prevention, Recommendations for Improving Medication Safety by Reducing Inappropriate Polypharmacy, https://perma.cc/ DR9T-F37F.
[30] Center for Health Law and Policy Innovation et al., FOOD IS MEDICINE RESEARCH ACTION PLAN (Jan. 2022), https://perma.cc/34VY-JSTX.

clinical evidence standard is adhered to.[31] And the expanded ICD-10 2023 code set creating Z91.110 – patient noncompliance with dietary regimen due to financial hardship – allows for even more meaningfully targeted benefit design.

IV. Coverage of Prescription Drugs as EHBs

The Affordable Care Act represented a promise that most people in the United States would be able to access high-quality, affordable health care coverage for themselves and their families.[32] This promise is realized in part by instituting a floor for most health care plans – requiring that they cover certain categories of benefits, including prescription drugs, and instituting a floor of minimum benefits. For prescription drugs, plans must cover at least one drug per class and category as dictated by a selected formulary, or the number covered by the state's benchmark plan per class and category.[33] We are encouraged that CMS is considering alternative formularies by which to determine whether plans satisfy benchmark standards in their coverage of prescription drugs as the current QHP certification process has shown much room for improvement.

For a consumer, the strength of a plan's formulary lies largely in whether the plan covers a robust number and variety of drugs without applying excessive restrictions that make these drugs unaffordable and inaccessible. Thus, it is critical that CMS use an accurate, accessible, and comprehensive formulary as a yard stick. Anything less allows room for formularies that pass administrative muster but provide little to no value to the consumer.

To this end, we believe the US Pharmacopeia's Drug Classification could provide a better alternative to the Medicare Model Guidelines (MMG) in conjunction with annual updates from CMS. The Drug Classification represents a formulary that is publicly available, accessible, and subject to annual comment and review. Conversely, although the USP MMG has long been familiar to insurance companies and federal and state regulators, it was not designed to serve as a benchmark for the average private insurance plan. Moreover, its use as a yardstick for QHPs has been difficult for advocates to follow, with CMS releasing annual documents that summarize changes to the drug list, including "newly prescribable drugs."[34]

It is important that whichever formulary CMS selects be subject to annual comment and review by the public, as drugs are often introduced and discontinued in the United States market. A formulary must be nimble enough to incorporate new drugs and shed drugs that have been discontinued. When a standard formulary does not remove drugs that have been discontinued, plans are able to technically meet the benchmark minimum requirements without offering the intended value. As an example, the MMG v.8 (submitted by the U.S. Pharmacopeial Convention in February 2020) removed Daklinza and Technivie from its formulary as these had been discontinued by their manufacturers.[35] The discontinuation of these drugs however, were announced in May 2018 (Technivie) and January 2019 (Daklinza). Because these two drugs were

[31] *See* Center for Health Law and Policy Innovation, ESSENTIAL HEALTH BENEFITS & NONDISCRIMINATORY BENEFIT DESIGN (Oct. 2022), https://perma.cc/3BR9-YDR4.
[32] Remarks by the President and Vice President at Signing of the Health Insurance Reform Bill (Mar. 23, 2010), https://perma.cc/39E2-7D77.
[33] 45 C.F.R. . § 156.122.
[34] *See, e.g.*, Essential Health Benefits RX Crosswalk, Methodology for Plan Year 2022, https://bit.ly/3wHQk2W.
[35] United States Pharmacopeia Medicare Model Guidelines v8.0 (showing changes from v7.0).

in the same category and class, plans would have been able to meet or largely meet benchmark requirements by covering these two discontinued drugs, leaving consumers without meaningful coverage of anti-hepatitis C DAAs they could actually obtain. Thus, the formulary selected as a yardstick for essential health benefits must have a standardized way for experts, manufacturers, and advocates to ensure and contribute to its integrity.

In its selection of a standard formulary, we urge CMS to consider whether the formulary's organization system (e.g., category and class structure) is comprehensive enough to ensure that plans cover enough *variety* of drugs to provide meaningful value to people living with chronic diseases. For example, the MMG v.7 had two classes of drugs used to treat hepatitis C: "Anti-hepatitis C (HCV) Agents, Other" and "Anti-hepatitis C (HCV) Agents, Direct Acting Agents". The MMG v.8 reorganized this grouping; the formulary removed drugs that were discontinued from the marketplace and reclassified other drugs that were no longer used to treat HCV. The MMG v.8 then combined the two groups to form one: "Anti-hepatitis C (HCV) Agents". This combination however now groups drugs that have drastically different roles in treating HCV. For example, sofosbuvir/velpatasvir (Epclusa) and glecaprevir/pibrentasvir (Mavyret) are both pan-genotypic DAAs that can be used to treat nearly all genotypes of hepatitis C (thus allowing people who do not require pre-treatment genotyping to begin treatment sooner).[36] The MMG v.8 combined group also houses the drug ribavirin, which is used to treat hepatitis C but is not effective alone and cannot be used by itself.[37] Thus, a plan that needs to meet only the one-drug-per-category/class minimum can meet this requirement by simply covering ribavirin and nothing else. The plan will have met its benchmark requirement while providing its members with no access to a full, effective course of HCV treatment.[38]

The USP Drug Classification formulary is not immune from overly broad drug classification categories. In fact, this formulary utilizes one group for all Anti-hepatitis C Agents, too. The Drug Classification also does not have a distinct category/class for preventive HIV drugs. Drugs like emtricitabine/tenofovir disoproxil fumarate (Truvada) and emtricitabine/tenofovir alafenamide (Descovy) have dual therapeutic uses – as treatment and as prevention – yet are only listed under the "Anti-HIV Combinations" alongside other drugs used to treat HIV infection.[39] Nevertheless,

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[36] EPCLUSA ("Sofosbuvir/velpatasvir: The only protease inhibitor-free, pangenotypic, panfibrotic hepatitis C regimen"), https://perma.cc/ZL7A-FH3E; MAVYRET ("Mavyret is a prescription medicine used to treat adults and children 3 years of age and older with chronic (lasting a long time) hepatitis C virus (hep C): Genotypes (GT) 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis"), https://perma.cc/3CSJ-SQYH; World Health Organization, CARE AND TREATMENT OF PERSONS DIAGNOSED WITH CHRONIC HEPATITIS C VIRUS INFECTION 8 (2018) ("The use of pangenotypic regimens obviates the need for genotyping before treatment initiation."), https://perma.cc/SUN2-65LA.

[37] MedlinePlus, Ribavirin (last revised June 15, 2016) ("IMPORTANT WARNING: Ribavirin will not treat hepatitis C (a virus that infects the liver and may cause severe liver damage or liver cancer) unless it is taken with another medication."), https://perma.cc/ZAD9-PDUA.

[38] While there are regulations that serve to discourage this kind of egregious formulary design, *see, e.g.*, 45 C.F.R. § 156.125(a); 45 C.F.R. § 156.122(a)(3) (establishing standards for plan pharmacy and therapeutics committees, including their responsibility to ensure that a plan's formulary "[c]overs a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states"), QHPs continue to be certified despite engaging in adverse tiering. Clearly, more robust EHB standards and enforcement of those standards is necessary to ensure that consumers, particularly those with chronic conditions, can access the medications they need.

[39] Other drugs like valproic acid are listed in multiple categories. USP Drug Classification formulary.

for the reasons discussed above, we recommend the Drug Classification formulary as superior to the currently utilized MMG.

Finally, in addition to improving the standard formulary used to determine category/class framework, we strongly urge CMS to consider a requirement that all or substantially all drugs within six protected classes (with exceptions for generic substitutions) be covered as part of the Essential Health Benefit prescription drug category. This requirement (already applicable to Medicare Part D plans) would help "mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations"[40] and directly address many of the barriers that people living with chronic illness and disabilities face in their health insurance coverage.[41]

Thank you for the opportunity to comment on the Proposed Rule. Our comments include citations to supporting materials, in many cases including direct links for CMS' benefit in reviewing our comments. We direct CMS to each of the sources cited and request their full consideration. Please e-mail mtomazic@law.harvard.edu with any questions.

Sincerely,

Maryanne Tomazic
Clinical Instructor
Center for Health Law and Policy Innovation

[40] Medicare Prescription Drug Benefit Manual Chapter 6, § 30.2.5.
[41] *See* National Health Law Program, Letter to Secretary Xavier Becerra (Dec. 6, 2021), https://perma.cc/2ZA9-ZUD7.