



January 27, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9911-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dr. Ellen Montz, Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Department of Health and Human Services

Re: RIN 0938-AU65, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023

Dear Administrator Brooks-LaSure and Director Montz:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG), a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. We are writing regarding the proposed rule (RIN 0938-AU65, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023) and offer the following recommendations in response.

Network Adequacy

HHCAWG commends the Department of Health and Human Services (HHS) for proposing new regulations to improve network adequacy among Qualified Health Plans (QHPs), which will help ensure that all enrollees, including those living with HIV, can have meaningful access to medically necessary services.

Application of time, distance, and wait time standards

We support the federal review of network adequacy for plans on the federally-facilitated exchange (FFE), save those states that perform plan management functions and elect to perform their own reviews, where such review would take place prior to certification. We also support the proposed post-certification review of wait times, in response to complaints and random sampling. The application of time, distance, and wait time standards is an important tool to ensure that people living with HIV and others have appropriate

access to primary care, infectious disease specialists, behavioral health services, and other services that are necessary for the effective management of HIV and other health needs.

We emphasize that HHS must ensure that, where states that perform plan management functions elect to apply their own network adequacy review, the standards and the process applied are thoroughly reviewed by HHS and determined to be at least as stringent as federal standards. This is necessary to ensure all QHP enrollees equally benefit from network adequacy requirements. Additionally, any network adequacy review, by HHS or the states, should include direct testing, such as through the use of secret shoppers, to verify the real-world availability of services.

In addition, we recommend HHS consider applying random sampling of plans to determine wait times *before* complaints are filed (including prior to the certification of plans and post certification, in order to determine ongoing compliance). Comprehensive pre-certification review is the most effective way to ensure enrollees are not subject to preventable accessibility issues. Furthermore, we encourage HHS to ensure there is a clear complaint process for enrollees to report network adequacy and accessibility issues. Transparency and publicity around this process is necessary to ensure these processes will be utilized and can effectively protect enrollee rights.

Finally, HHS should require coverage for out-of-network providers at in-network cost sharing if a qualified specialist, including a qualified HIV provider, is not available within network according to network adequacy standards. Similarly, enrollees should be held financially harmless for seeking care from higher tier providers when providers are otherwise unable to meet time and distance standards or appointment wait time standards.

Provider types subject to network adequacy requirements

We strongly support HHS' proposal to include within the regulations the provider and facility types that are subject to time and distance standards, to ensure timely and meaningful access to providers, including infectious disease providers. When HIV is managed by experienced HIV clinicians, including HIV-experienced infectious disease providers, people have better outcomes and more cost-effective care.¹ Narrow networks and barriers to accessing providers undermine the ability of people living with HIV to receive the timely and appropriate care and treatment that is critical to their health and quality of life.

People living with HIV also are affected by the network adequacy requirements as they are applied to other types of providers. It is important that enrollees have access to robust networks of providers to ensure care is available to meet the needs of the whole person. For example, considering the impact of the COVID-19 pandemic and the increased demand for emergency and urgent care services, and the risk COVID-19 poses to individuals who are immunocompromised,² we support HHS' proposal to include emergency medicine and urgent care as additional specialties for which plan networks must adhere to time and distance standards.

Similarly, we strongly support the inclusion of outpatient clinical behavioral health on the list of specialties that must adhere to time and distance standards. However, we urge HHS to split this category into two

¹ Julia M. Rackel et al., *Provider training and experience for people living with HIV/AIDS*, 15 COCHRANE DATABASE OF SYSTEMIC REV. CD003938 (2011).

² Ali Haider Mohammed, Ali Blebil, Juman Dujaili, & Bassam A Rasool-Hassan, *The Risk and Impact of COVID-19 Pandemic on Immunosuppressed Patients: Cancer, HIV, and Solid Organ Transplant Recipients*, 22 AIDS REV. 151 (2020).

provider types, in recognition that they require unique specialty training. We recommend creating an “outpatient clinical mental health” provider category and a separate “outpatient clinical substance use disorder” provider category. Putting all behavioral health providers into one category will cover up shortages of either mental health or substance use disorder service providers, and most behavioral health providers do not offer both mental health and substance use disorder services.

Furthermore, we encourage CMS to add pharmacies, including brick-and-mortar pharmacies, to the list of facilities that are subject to time and distance standards. Access to physical pharmacies, as opposed to mail order pharmacies, is critically important for many people living with HIV, who need the opportunity to consult with expert pharmacists that are familiar with their treatment regimens and medical histories.³ Additionally, access to physical pharmacies is important to avoid complications associated with mail order pharmacies for some people with HIV, including damage to medications⁴ and privacy concerns.

Finally, we recommend adding a category for providers of gender-affirming surgery. While some general surgeons or plastic surgeons provide these procedures, many do not, and it can be difficult for transgender QHP enrollees to identify providers of gender-affirming surgeries.

We strongly support HHS’ proposal that, for plans that use tiered networks, only those providers contracted within the lowest cost-sharing tier may count toward the plan’s ability to satisfy their network adequacy obligations. True access to care cannot exist when providers and facilities are “in-network” in name, but otherwise unaffordable to enrollees.

Access to information about telehealth services

We support HHS’s proposal to require all issuers to submit information about whether network providers offer telehealth services. During the COVID-19 pandemic, we have learned more about the benefits and challenges associated with expanded use of telehealth, and gathering additional information will help inform future rulemaking about the role of telehealth providers in comprising a network sufficient to deliver covered services to enrollees. However, while telehealth can be an important tool to address limited provider and specialist availability in an area, we do not recommend it as a substitute for having access to in-person provider visits within a reasonable travel time and distance as an option particularly if there are local providers available. We urge caution in incorporating telehealth providers who will solely be available via telehealth unless there are other in-network provider options available locally or if the telehealth provider can offer expertise otherwise not available. To allow remote access to providers as a substitute for locally available providers could widen health disparities without strong safeguards in place and attention to addressing the digital divide. We believe that more information is needed before rulemaking in this area would be prudent, and thus support the proposal to collect this information.

Application of federal network adequacy requirements to plans on state exchanges

We believe that in future rulemaking, HHS should consider establishing the same standards for state based exchanges as it uses in the FFE, while allowing states to perform their own reviews of network adequacy

³ Patricia Murphy et al., *Impact of HIV-Specialized Pharmacies on Adherence and Persistence with Antiretroviral Therapy*, 26 AIDS PATIENT CARE AND STDs 526 (2012).

⁴ Press Release, American Society of HealthSystem Pharmacies, *Mail-order Medications Often Exposed to Unsafe Temperatures, Study Shows* (Dec. 9, 2020), <https://perma.cc/2TLJHKKH> (describing a study that found that shipped medications were subject to unsafe temperatures).

as long as both the standards and review process are at least as stringent as the established federal standards and process. As HHS notes in the Notice of Benefit and Payment Parameters (NBPP), network adequacy standards across states exchanges are inconsistent, and 25% of those states lack any quantitative standard for time, distance, or wait times.⁵ Consistent standards across all exchanges will protect access and ensure that all enrollees, regardless of the state in which they live, have full access to medically necessary services.

Essential Community Providers (ECP)

Ryan White HIV/AIDS Program providers – who are listed as an ECP – provide the clinical foundation for HIV care and treatment in the United States serving more than 50% of people with HIV in the U.S. We support HHS’ proposal to raise the ECP participation standard to 35%. Additionally, we urge HHS to require QHPs to meet this standard for *each* category of ECP rather than for all ECPs taken as a whole, to ensure that QHP enrollees have adequate access to all of the important types of ECPs, including Ryan White providers. We encourage HHS to monitor and enforce these contracting requirements, including by collaborating with the HRSA HIV/AIDS Bureau to ensure that issuers are contracting with Ryan White HIV/AIDS Program clinical providers and to promote best practices for clinical care for QHP enrollees.

We strongly support HHS’ proposal that for plans that use tiered networks, to count toward the issuer’s satisfaction of the ECP standards, ECPs must be contracted within the network tier that results in the lowest cost-sharing obligation. We also support the inclusion of substance use disorder treatment centers as eligible to fulfill the “other ECP providers” contracting obligation. Further, consistent with our recommendation above, we encourage HHS to strengthen the ECP requirements such that the 35% participation standard applies to each ECP category, including substance use disorder treatment centers.

Nondiscrimination in Health Plan Design

The proposed NBPP for 2023 seeks to refine Section § 156.125 of the Affordable Care Act (ACA), directly addressing the issue of discriminatory benefit design, intending to ensure that insurance plans do not discriminate against people living with chronic illness. Although the ACA already prohibits health insurers from discriminating against people with pre-existing conditions, the HIV community has experienced health plans designed strategically to deter enrollment of patients with high medical needs.⁶ Issuers have structured benefits that apply adverse tiering and high cost-sharing for specialty prescription drugs (including component drugs for guidelines treatment regimens), or exclusions for necessary treatments.

Clarifying the requirements and providing a regulatory framework to evaluate plan benefit design that is based on clinical guidelines and evidence is the appropriate approach to enhance compliance. However, we urge CMS to ensure that, in advancing the goals of nondiscrimination in plan design, the clinical

⁵ Centers for Medicare and Medicaid Services, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment, Proposed Rule (January 5, 2022), at 272, <https://perma.cc/GF62-3DCD>.

⁶ The AIDS Institute, The National Health Law Program. Administrative Complaint: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida. (May 29, 2014). <https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:5414340a-9434-48f6-9fd2-373310b35814>. See also 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://chmpi.org/news-and-events/news-and-commentary/commentary/chlpi-launches-groundbreaking-campaign-enforce-health-care-rights-people-living-hiv-seven-states/>.

evidence used is not biased or discriminatory itself. It is noted that in the description of evidence-based sources, including current and relevant peer-reviewed medical journal article(s), practice guidelines, and recommendations from reputable governing bodies, that the term “standard of care” is specifically avoided. In some instances, standards of care are the leading guidance for treatment.⁷ This expansion of trusted sources would ensure that the clinical justification meets the most up-to-date evidence-based practices.

Furthermore, while we support CMS’ intention to ensure that benefit designs do not discriminate against people with high health care needs, we strongly urge CMS to include language in this section also prohibiting use of copay accumulator adjustment policies, which discriminate against people living with chronic illness. Copay accumulator adjustment policies undermine Affordable Care Act protections prohibiting insurers from charging people with pre-existing conditions more than healthier enrollees. Copay assistance is generally only available for specialty medications, which are used by people with serious, complex chronic illness. These policies subvert the benefit of co-pay assistance, thereby discriminating against people living with chronic conditions. People with low incomes and people of color are more likely to be living with a chronic illness,⁸ and therefore, these policies target the most vulnerable patients, enabling insurance issuers to engage in what amounts to “backdoor” underwriting of insurance policies for people who use specialty medications. While CMS notes that adverse tiering is discriminatory and that coverage of specialty drugs and placement of those drugs on a formulary are important factors to determine whether a plan is discriminating against people with chronic illness, copay accumulator adjustment policies put specialty drugs out of reach, even when covered.

Nondiscrimination Based on Sexual Orientation and Gender Identity

HCAWG strongly supports HHS’ proposal to amend 45 CFR 147.104, 155.120(c), 155.220(j), 156.200(e), and 156.1230(b) to clarify that nondiscrimination protections explicitly prohibit discrimination on the basis of sexual orientation and gender identity. Individuals in the Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI) community often face discrimination when accessing health care, resulting in poorer health outcomes. For example, studies have shown that LGBT people often have higher rates of chronic health conditions and encounter barriers to care exacerbated by stigma and discrimination.⁹

⁷ The World Professional Association for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. Standards of Care V.7. <https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf>.

⁸ The Center for American Progress. Fact Sheet: Health Disparities by Race and Ethnicity. (May 7, 2020). <https://www.americanprogress.org/article/health-disparities-race-ethnicity/>

⁹ See, e.g., Kellan Baker & Jeff Krehely, How Health Care Reform Will Help LGBT Elders, 21 PUBLIC POLICY & AGING REPORT 19 (2011); Walter O. Bockting, et al., Stigma, Mental Health, and Resilience in an Online Sample of the US Transgender Population, 103 Am. J. Pub. Health 943, 943 (2013); Cecilia Chung, et al., Transgender Law Center, Positively Trans: Initial Report of a National Needs Assessment of Transgender and Gender Non-Conforming People Living with HIV (2016), <http://transgenderlawcenter.org/wp-content/uploads/2016/02/PositivelyTrans-2015-7-border-FINAL.pdf>; Andrew Cray, et al., Center for American Progress, Seeking Shelter: The Experiences and Unmet Needs of LGBT Homeless Youth 18-19 (2013), <https://cdn.americanprogress.org/wp-content/uploads/2013/09/LGBTHomelessYouth.pdf>; Ann P. Haas, et al., Suicide Attempts Among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey 2 (2014), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/AFSP-Williams-Suicide-Report-Final.pdf> (finding that

Explicit protections against discrimination on the basis of sexual orientation and gender identity will create safer opportunities for people, including people living with HIV, to access nondiscriminatory and medically appropriate care and help address ongoing disparities that members of the LGBTQI community experience in the health care system.

HHCAWG agrees that the proposed regulatory amendment is within HHS' authority and consistent with the ACA's intent to improve access to health coverage and services and to prohibit discrimination in the provision of health care. Congress intended the ACA to prohibit unreasonable barriers to obtaining appropriate medical care and remove limits on the availability of the full scope of health care a person needs.¹⁰ Recent amendments to these sections ran contrary to these aims and should be reversed.¹¹ However, the proposed regulatory amendments must be accompanied with a concerted effort to monitor and enforce nondiscrimination protections. Plans sold on the Marketplace have historically contained categorical exclusions and language that considers certain gender-affirming services as cosmetic (and therefore not covered as a benefit). HHS should ensure that all plans certified to be sold as a Qualified Health Plan do not otherwise have policies that unfairly restrict or exclude gender-affirming care for enrollees.

HHCAWG also recommends HHS amend sections 147.104(e), 155.120(c), 155.220(j)(2)(i), 156.200(e), and 156.1230 to expressly prohibit discrimination on the basis of sex characteristics (including intersex traits). This approach would be consistent with the recent Title X family planning program final rule¹², as well as HHS' past interpretation of Section 1557 of the ACA.¹³ Discrimination based on sex characteristics, including intersex traits, is necessarily discrimination on the basis of sex. Following *Bostock*, the Department of Justice updated its *Title IX Legal Manual* to clarify that the *Bostock* Court's reasoning "applies with equal force to discrimination against intersex people," concluding:

Discrimination against intersex individuals is similarly motivated by perceived differences between an individual's specific sex characteristics and their sex category (either as identified at birth or some subsequent time). Additionally, discrimination based on anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, and hormone function) is inherently sex-based. Intersex traits, like gender identity and sexual orientation, are "inextricably bound up

survey respondents living with HIV (51%), survey respondents living with disabilities (55-65%), and survey respondents who have had a health care provider refuse to treat them due to their gender identity (60%) had higher prevalence of suicide attempts); Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination against LGBT People and People With HIV 9-16* (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf; Ilan H. Meyer, *Why Lesbian, Gay, Bisexual, and Transgender Public Health?*, 91 AM. J. PUB. HEALTH 856, 856-57 (2001); Office of Disease Prevention and Health Promotion, *Lesbian, Gay, Bisexual, and Transgender Health*, <https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health> (last visited Aug. 13, 2019); Cigna, *LGBT Health Disparities* (Feb. 2017), <https://www.cigna.com/individuals-families/health-wellness/lgbt-disparities>.

¹⁰ Pub. L. No. 111-148, sec. 18144 [Section 1554 of the ACA].

¹¹ *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority*, 84 Fed. Reg. 37,160 (June 19, 2020).

¹² HHS, *Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services*, 86 FR 56144, 56159, 56178 (Oct. 7, 2021), *to be codified at* 42 CFR § 59.5.

¹³ HHS, *Nondiscrimination in Health Programs and Activities* 81 FR 31375, 31389 (May 18, 2016) ("the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics").

with” sex. In other words, it is impossible to discuss intersex status without also referring to sex. Lastly, discrimination based on intersex traits may also involve sex stereotypes, as intersex people by definition have traits that do not conform to stereotypes about male or female bodies.¹⁴

Like other LGBTQI populations, intersex people face pervasive health and health care disparities, and face barriers to receiving appropriate health care and coverage.¹⁵ As with sexual orientation and gender identity, HHS has statutory authority independent of Section 1557 to prohibit discrimination based on sex characteristics, including intersex traits, by Exchanges, issuers, and agents and brokers. Discrimination against intersex people in health insurance can take a number of forms, and the HHS should provide one or more illustrative examples, such as: (1) benefit designs that restrict coverage of EHB solely due to sex characteristics (including intersex traits) (for example, categorically excluding intersex adults from clinical policies for gender affirming care), and (2) benefit designs that restrict coverage of Essential Health Benefits due to gender coding in a manner that limits care for a transgender or intersex individual who possesses the relevant anatomy and otherwise meets criteria for coverage.

Standardized Benefit Design

HHCAGW is acutely aware of how affordability and accessibility of healthcare remains a major barrier to ending the HIV epidemic. HHCAGW supports proposals that will lower out-of-pocket costs for people living with HIV, and is pleased to see CMS reinstate standardized benefit plans with flat dollar copayments for specialty medications. However, we are concerned that the dollar amounts for specialty medications – while a significant improvement at every metal level over the high coinsurance amounts found in current marketplace plans – remain too high for many patients struggling to afford their medications without copay assistance. Research has shown that over 70% of patients will not fill a prescription when their copayment reaches \$250 (the amount proposed for specialty medications in gold level standard plans), and even at half that amount (\$125), 55% of patients will opt against filling a new prescription.¹⁶

The copay amounts proposed for standard plans ranges from \$150 - \$350 per fill. And because most plans require enrollees to meet their deductible (proposed at \$2,000 - \$9,100), people living with HIV will still face steep out-of-pocket costs that make adhering to a treatment plan difficult, if not impossible without copay assistance. Some aspects of the proposed details of the standard plan design look promising and could be extended across the different metal levels. For example, some prescription drug tiers are not subject to the deductible; but for the most-costly prescription category, specialty drugs, the cost-sharing is still subject to the deductible.

Additionally, we believe this proposal could be strengthened by 1) ensuring that patient copay assistance is counted toward the deductible and out-of-pocket limit, and 2) excluding all specialty drugs from the

¹⁴ US Department of Justice, *Title IX Legal Manual* (updated Aug. 12, 2021) (internal citations omitted), <https://www.justice.gov/crt/title-ix#Bostock>.

¹⁵ Rosenwohl-Mack A, et al., A national study on the physical and mental health of intersex adults in the U.S., *PLoS ONE* 5(10):e0240088 (2020); Zeeman, L., & Aranda, K., A Systematic Review of the Health and Healthcare Inequalities for People with Intersex Variance, *Int. J. Environ. Res. Public Health*, 17:6533 (2020); *National Academies, Understanding the Well-Being of LGBTQI+ Populations*, (Washington, DC: National Academies Press 2020).

¹⁶ IQVIA. *Medicine Use and Spending in the U.S: A review of 2018 and Outlook to 2023*. (May 9, 2019). <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>.

deductible to make medications more affordable to patients who utilize this category of prescription to maintain their health.

Copay Assistance Programs

Patient copay assistance is a lifeline for people living with chronic illnesses like HIV to afford critical, life-saving medications. As insurers have shifted more and more costs to enrollees – especially those who rely on specialty medications – with higher deductibles and increasing coinsurance, many people living with chronic illness must rely on financial assistance to help cover the costs of their prescription drugs and remain adherent to their prescribed treatments. While most enrollees will never hit an out-of-pocket limit of \$9,100 (the proposed amount for 2023), people managing a chronic illness requiring specialty medications may be forced to pay this amount *every single year*, often in the first few months of the year.^{17,18} Since most Americans do not have an extra \$9,100 after they pay their health insurance premium, rent or mortgage, food, transportation, childcare, and other basic needs, copay assistance is often the only way they can afford the medication they need, even if they have insurance.¹⁹

Some descriptions liken copay assistance to a coupon or a discount for prescription drugs. However, it is important to note that unlike a coupon or discount, copay assistance does not reduce the amount that enrollees are charged by their insurance plan for a prescription drug; rather, it is a source of financial aid to help patients pay the cost-sharing their insurance plan requires to fill their prescription. And unlike other large out-of-pocket costs for covered services, cost-sharing for a prescription drug must be paid in full for a person to receive the product, rather than being billed afterwards. This poses an insurmountable financial barrier for many patients, with devastating potential consequences.

Extensive research documents that high out-of-pocket costs are associated with prescription abandonment, delaying treatment, or rationing doses.²⁰ For patients with a serious condition like HIV, multiple sclerosis, cancer, epilepsy, or hemophilia, delaying or forgoing treatment may result in severe deterioration of their condition, permanent disability or even death. Copay assistance helps patients adhere to prescribed treatment, improving or maintaining their health.

Helping patients adhere to medications and treatment regimens lowers costs to the overall healthcare system as well. A recent study found that increasing use of utilization management policies costs health

¹⁷ Center for Consumer Information and Insurance Oversight, *Affordability in the Marketplace Remains an Issue for Moderate Income Americans*. (January 2021). <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Impact-Premium-Affordability.pdf>.

¹⁸ K. Hempstead. *Marketplace Pulse: Cost-Sharing in the Marketplace, 2021*. Robert Wood Johnson Foundation, (June 28, 2021), <https://www.rwjf.org/en/library/research/2021/06/marketplace-pulse-cost-sharing-in-the-marketplace-2021.html>.

¹⁹ Board of Governors of the Federal Reserve System, *Report on the Economic Well-Being of US Households in 2019-May 2020*. <https://www.federalreserve.gov/publications/2020-economic-well-being-of-us-households-in-2019-overall-economic-well-being-in-2019.htm>.

²⁰ IQVIA. *Medicine Use and Spending in the US: A Review of 2018 and Outlook to 2023*. (May 2019.) [Medicine Use and Spending in the US; A Review of 2018 outlook to 2023](#). A recent patient experience survey showed that of respondents taking prescription medicines with a high-deductible health plan, 52% report one or more episodes of non-adherence in the past year (Patient Experience Survey https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PES-Report_100621_Final.pdf).

care stakeholders \$93 billion annually, with patients bearing the brunt through increased cost-sharing.²¹ Any economic benefits gained by implementing obstructive policies, including copay accumulator adjustment policies, come at the cost of patients' health.²²

"Double-Dipping" by Insurers using Copay Accumulator Adjustment Policies

In addition to the harm caused to patients by copay accumulator adjustment policies, these policies subvert the patient protections of the ACA by allowing insurers and PBMs to overcharge enrollees who use copay assistance. The ACA established annual out-of-pocket limits for covered health care services. When enrollees hit the out-of-pocket limit, insurance issuers must fully cover any further health care costs incurred. By not counting cost-sharing amounts used to pay for covered services toward annual deductibles and out-of-pocket limits, insurers are able to keep the cost-sharing paid by enrollees, while avoiding responsibility for costs above the out-of-pocket limit. This reduces the overall value of insurance for enrollees with chronic illness and exposes them to ongoing charges for their prescription drugs as well as any other health care they may need during the year.

In other rulemaking, CMS has acknowledged that insurers using copay accumulator adjustment policies are benefiting financially from those payments, subverting the intended benefit to the enrollee. Nonetheless, CMS' position puts the onus on the manufacturer to find new ways to ensure that any benefit from copay assistance provided is accrued to the enrollee, or face penalties.²³ The simplest way to address this concern, however, would be for HHS to restrict the use of copay accumulator adjustment policies, as it did in the 2020 NBPP, ensuring that enrollees get the full benefit of copay assistance intended for them.

Reinstating HHS' Original Position on Copay Assistance

This issue has been addressed by CCIIO in previous iterations of the NBPP. In the 2020 NBPP, CCIIO restricted use of copay accumulator adjustment policies, allowing them only in cases where an enrollee used manufacturer copay assistance for a brand drug when a medically-equivalent generic is available. However, HHS reversed course in the 2021 NBPP, allowing issuers to disregard any and all manufacturer copay assistance when determining whether an enrollee has met their annual deductible and/or out-of-pocket limit. This reversal of policy position has put our patients in a precarious position as they make difficult decisions about paying for medicines, and paying for other necessities like groceries and rent.

HHS justified the policy reversal as necessary to protect access to tax benefits for people who use Health Savings Accounts (HSAs) with a High Deductible Health Plan (HDHP). A complete reversal of HHS' policy

²¹ R. King. *Study: Drug utilization costs health industry \$93B a year, with patients bearing most of the cost*. Fierce Healthcare. (August, 4, 2021). <https://www.fiercehealthcare.com/payer/study-drug-utilization-costs-health-industry-93b-a-year-patients-bearing-most-cost>.

²² R.I. Carlton, T. Bramley, B Nightengale, T. Conner, C Zacker. *Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy*. (American Journal of Pharmacy Benefits.) (January, 2010). <https://www.asponline.org/wp-content/uploads/2021/08/Review-of-Outcomes-Associated-With-Formulary.pdf>

²³ US Department of Health & Human Services. *Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third- Party Liability Requirements*. <https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based-0>.

was not needed to protect HSA tax benefits. The IRS has since clarified that its only concern is related to the use of copay assistance to meet the minimum deductible to qualify as an HDHP (\$1,400 for an individual or \$2,800 for a family).²⁴ The use of copay assistance for amounts over the minimum deductible does not conflict with its policy related to HSA-eligibility. In its 2020 policy, HHS had already described certain conditions under which it would allow issuers to apply copay accumulator adjustment policies; rather than reverse its policy completely, HHS should have simply allowed plans to implement these policies up to the minimum deductible for enrollees in HSA-eligible plans.

We urge HHS to reconsider its policy allowing insurers and PBMs to adopt copay accumulator adjustment programs. A recent review of 2020 and 2021 marketplace plans reveals that copay accumulator adjustment programs have proliferated in the past two years.²⁵ These policies disproportionately impact patients with chronic illness, jeopardizing their access to needed care and prescription drugs. We urge HHS to require issuers and pharmacy benefit managers to count patient copay assistance toward a beneficiary's out-of-pocket costs, putting patients' health first.

Health Equity, Climate Health, and Qualified Health Plans

HHCAGW strongly supports requirements for QHPs to collect information on each enrollee's race, ethnicity, gender, sexual orientation, primary language and disabilities. Asking enrollees to provide this information is necessary to illuminate persistent health inequities and to monitor those that are yet unidentified. HHS – for all of its programs and not solely marketplaces – should review expert recommendations and research on demographic data collection and set standards for the language used by QHPs to collect data. Recommendations already exist from the [Institute of Medicine](#), [the Williams Institute at UCLA](#),²⁶ and forthcoming from the [National Academies of Sciences, Engineering, and Medicine](#) that draw on both studies and stakeholder input.

The ultimate purpose of collecting demographic information from enrollees is to advance health equity. HHS should set expectations for QHPs to engage in systematic review of enrollee data and in taking actions to correct disparities that become apparent through this review. It is crucial that QHPs take affirmative responsibility for addressing disparities in health outcomes and access to treatment. HHS should also review the data collected by QHPs as part of an evaluation of whether some enrollees are experiencing gaps in services.

Certain populations in the United States, including Black and Latinx communities, gay and bisexual men, and transgender women, continue to bear a disproportionate burden of the HIV epidemic in this country,

²⁴ IRS. Notice 2004-50. Health Savings Accounts – Additional Qs & As. (Revised August 9, 2004), <https://www.irs.gov/pub/irs-drop/n-04-50.pdf>.

²⁵ Stephanie Hengst. The AIDS Institute. *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients*. June 2020, http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf.

²⁶ *Data Collection Methods for Sexual Orientation and Gender Identity*, WILLIAMS INSTITUTE, UCLA SCHOOL OF LAW (March 2016), <https://perma.cc/5PDZ-CR3S>; *Best Practices for Asking Questions about Sexual Orientation on Surveys (SMART)*, WILLIAMS INSTITUTE, UCLA SCHOOL OF LAW (November 2009), <https://perma.cc/CSU8-PFB5>; *Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys (GenIUSS)*, WILLIAMS INSTITUTE, UCLA SCHOOL OF LAW (September 2014), <https://perma.cc/KSE7-JEZE>.

while also having less access to necessary treatment and prevention options.²⁷ These disparities based on race, gender, and sexual orientation are further exacerbated by long-standing health inequities and the multiplicative impact of intersectional stigmas and prejudices.²⁸ Engaging community leaders in data collection efforts and analysis can help policymakers understand how to best address barriers to access and ultimately promote meaningful access to services for all people.

Additionally, HHS requested comment on whether QHPs should be required to obtain NCQA's Health Equity Accreditation. We support this requirement. HEA's standard for accreditation captures the importance of data collection and affirmative steps that QHPs can take to use health disparity data to improve health equity. However, the HEA lacks specific standards that address people with disabilities. We recommend HHS work with NCQA and community members to add standards that promote equity for enrollees with disabilities. HHS should retain responsibility for oversight of QHP accreditation, and materials provided to NCQA by QHPs, such as scorecards and evaluations, should be publicly available.

Impact of Past-Due Premiums

HHCAWG is supportive of the proposed interpretation of the guaranteed availability requirement that does not allow insurers to deny enrollment due to an individual's failure to pay past premium debt. As noted in the proposed rule, these protections are particularly important for low and middle-income individuals and individuals who face financial instability due to domestic violence, crime, incarceration, multiple chronic conditions, medical emergencies, and the COVID-19 pandemic. Insurers have other tools available to recoup unpaid premiums without denying enrollment and delaying or disrupting necessary health care.

Elimination of Special Enrollment Period Verification

HHCAWG urges HHS to eliminate special enrollment period verification (SEP-V) for all Exchanges, and return to the special enrollment period (SEP) application and verification standards that were in place prior to the 2017 Market Stabilization Rule. The 2017 Market Stabilization Rule imposed burdensome verification requirements for enrollees using certain SEPs to enroll in or make changes to their coverage. This change was made despite no credible evidence of widespread SEP abuse by ineligible consumers and overwhelming evidence that burdensome documentation requirements are a barrier to accessing coverage. SEP-Vs can delay the start of coverage for people seeking coverage on the Marketplace, which can unfairly burden consumers and disrupt and delay access to life-saving services.

As noted in the Proposed Rule, SEP-Vs have a disproportionate impact on Black and African American consumers and can negatively impact the risk pool because younger, often healthier adults are less likely to submit the requisite documentation. Despite these acknowledgements, HHS not only encourages State Exchanges to conduct SEP-Vs, but also proposes to allow Exchanges on the Federal Marketplace to continue to conduct SEP-Vs in the most commonly used special enrollment period (loss of minimum essential coverage). We find this counter to Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government), which includes a goal to redress inequities in policies, and Executive Order 14009 (Strengthening Medicaid and the Affordable Care Act), which states the policy of the Administration is "to make high-quality healthcare accessible and

²⁷ News Release, National Institutes of Health, *To end HIV epidemic, we must address health disparities* (Feb. 19, 2021), <https://perma.cc/3ZE6-HBSG>.

²⁸ Kali Villarosa, *Intersectionality and the Future of HIV/AIDS: Social and health inequities weaponize the impact of epidemics on Black people*, BLACK AIDS INSTITUTE (2021), <https://perma.cc/DJQ6-5BG8>.

affordable to every American.” We urge HHS not to implement policies that are already known to have a disproportionate impact on Black and African American consumers and that would restrict timely access to health care benefits.

Thank you for the opportunity to provide feedback and for your thoughtful consideration of these comments. If you have further questions, please reach out to HHCAWG co-chairs Maryanne Tomazic (mtomazic@law.harvard.edu) with the Center for Health Law and Policy Innovation and Rachel Klein (rklein@tmail.org) with The AIDS Institute.

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