PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

January 27, 2022

VIA ELECTRONIC FILING — *http://www.regulations.gov*

The Honorable Xavier Becerra
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS–9914–P, Mail Stop C4–26–05
Baltimore, MD 21244-1850

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, CMS-9911-P

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the 2023 Notice of Benefit and Payment Parameters (NBPP) proposed rule published by the U.S. Department of Health and Human Services (HHS).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.

Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment. Inequities are often rooted in community-level factors like where we live, work, and play; lack of adequate coverage and access to providers; and systemic racism and discrimination. There are myriad and intersecting systemic social and structural barriers that impede equitable access to medicines, and we believe improving health insurance coverage to make treatments more accessible and affordable for everyone is one of the most important things that can be done right now to improve equity in health care access and outcomes. Many patients in the United States, including those with health insurance coverage, face exorbitant out-of-pocket costs for their medicines. For disadvantaged and socioeconomically deprived communities, the eroding value of health insurance can exacerbate delays in diagnosis and access to medicine, further widening disparities in health outcomes.

[1] 87 Fed. Reg. 584 (Jan. 5, 2022).

During the COVID-19 public health emergency, access to comprehensive, affordable, and accessible prescription drug coverage has been more important than ever. Affordable access to medicines is crucial in preventing, treating, and potentially curing acute and chronic medical conditions, as well as improving quality of life and reducing spending on other health care services. Recent research shows that today, many Americans face affordability challenges in accessing the brand medicines they need in part because of health plans' increased use of benefit designs utilizing high deductibles and coinsurance. Across the seven therapeutic areas included in a recent analysis of IQVIA data, patients with deductibles and/or coinsurance paid as much as 30 times more out of pocket annually for brand medicines than patients with only copays.[2] The increasing use of deductibles and coinsurance by health plans disproportionately burdens patients with chronic conditions who are prescribed brand medicines, including some of the most disadvantaged in the health system.[3] For example, research from Harvard University shows that reduced cost sharing for cardiovascular medicines increased adherence and had a greater impact on reducing the risk of vascular events and medical costs among nonwhite patients.[4]

We support many of the proposals in the proposed 2023 NBPP that would help improve the affordability of and access to health care, particularly among disadvantaged populations. However, more needs to be done to counteract current trends in benefit design that are shifting more and more costs for medicines to patients and exacerbating health disparities. We stand ready to work with this Administration toward this important goal.

PhRMA has the following specific comments, which we discuss in greater detail below:

- *Annual Limit on Cost Sharing.* Under the Affordable Care Act (ACA), group health plans and health insurance issuers must count cost sharing for essential health benefits – including third-party payments and manufacturer cost-sharing assistance – toward the annual limitation on cost sharing.[5] HHS's actions in the prior Administration have significantly undermined this important patient protection. HHS should reverse the policy finalized in the 2021 NBPP[6] and replace it with the earlier finalized policy from the 2020 NBPP final rule,[7] which limited the circumstances in which health insurance issuers and group health plans may exclude manufacturer cost-sharing assistance from accumulating toward the annual limit on cost sharing.
- *Health equity.* PhRMA applauds HHS's focus on health equity and appreciates that questions regarding the advancement of health equity are included in many sections of the proposed rule. Health disparities are not attributable to any one flaw in health care

[2] PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost sharing-for-Brand-Medicines.pdf.
[3] Megan B. Cole, PhD, MPH; Jacqueline E. Ellison, MPH; Amal N. Trivedi, MD, MPH; "Association Between High-Deductible Health Plans and Disparities in Access to Care Among Cancer Survivors," JAMA, June 2020.
[4] Choudhry, NK., Bykov, K., Shrank, WH., et al. Eliminating medication copayments reduces disparities in cardiovascular care. *Health Affairs* 2014 33:5, 863-870. https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0654.
[5] ACA § 1302(c)(3), 42 U.S.C. § 18022(c)(3).
[6] 85 Fed. Reg. 29164, 29230 (May 14, 2020).
[7] 84 Fed. Reg. 17454, 17544 (Apr. 25, 2019).

coverage or access and thus must be addressed using a variety of tools and methods. PhRMA makes several suggestions for HHS to consider as it undertakes the crucial work of advancing health equity and looks forward to further engagement on these issues.

- *Standardized Plans.* PhRMA agrees with HHS's proposal to require Qualified Health Plans (QHPs) to offer standardized benefit designs on Federally-Facilitated Exchanges (FFEs) and State-Based Exchanges using the federal platform (SBE-FPs). We believe the cost-sharing structures of the proposed plans will greatly increase affordability and access to health care. However, we believe that the proposed silver plans can be further improved, while maintaining equivalent actuarial value (AV).
- *Essential Health Benefits.* PhRMA agrees with HHS's proposals on essential health benefits (EHBs), including ending the flexibility for substitution of benefits across benefit categories and establishing a more detailed definition of discriminatory benefit designs, which requires that benefit designs be clinically based and not based solely on cost. PhRMA also supports the HHS confirmation that "adverse tiering" (placing all or most drugs for a particular condition on the highest cost sharing tier) is presumptively discriminatory. In the detailed comments that follow, PhRMA recommends additional benefit design and plan practices that should be considered presumptively discriminatory and offers additional tests HHS should adopt to evaluate plan designs and formularies.
- *Actuarial Value Threshold.* PhRMA supports the proposed changes to the AV threshold to ensure plan metal levels conform more closely with the required AVs and to reduce confusion about the differences between plans.
- *Annual Eligibility Determinations.* PhRMA agrees with HHS that the inclusion of cost-sharing factors in annual redetermination eligibility guidelines would be beneficial for Exchange enrollees.
- *Risk Adjustment.* PhRMA welcomes the continued inclusion of prescription drug categories in the risk adjustment model.
- *Network Adequacy.* PhRMA supports federal network adequacy standards for QHPs and encourages HHS to include pharmacy networks in those reviews.
- *Essential Community Providers.* PhRMA believes a more robust standard for inclusion of essential community providers in provider networks will promote health equity.
- *Web-Brokers.* PhRMA supports more robust disclosures and transparency by web-brokers to facilitate informed patient choices among health plans.

Please find our detailed comments on specific sections of the proposed rule below.

****

Annual Limit on Cost Sharing (§ 156.130)

PhRMA remains deeply concerned about HHS's arbitrary reversal in the 2021 NBPP final rule to permit group health plans and health insurance issuers to use accumulator adjustment programs without limitation,[8] which has likely resulted in higher out-of-pocket prescription drug costs for millions of patients.[9] This policy allows plans and issuers to exclude the value of manufacturer cost-sharing assistance from accruing toward the statutorily required annual limitation on cost sharing regardless of whether a medically appropriate generic equivalent is available. Historically, such cost-sharing assistance has counted toward the annual limitation on cost sharing under the ACA, which helps protect enrollee access to medically necessary treatment options. The current policy undermines this important patient protection under the ACA that provides patients and families with greater predictability and certainty about their maximum out-of-pocket exposure on an annual basis. Numerous stakeholders have raised concerns about this policy, including several bipartisan Members of Congress who have introduced the Help Ensure Lower Patient (HELP) Copays Act to reverse the 2021 NBPP policy.[10]

Further, the 2021 NBPP's policy change compromises patients' ability to adhere to prescribed medicines at a moment when insurance coverage for medicines continues to erode. It puts patient health and financial security in danger, and it runs directly counter to the important policy goals of lowering patient out-of-pocket costs for prescription drugs and taking steps to eliminate disparities in health care access and outcomes. One study found that, on average, cost-sharing assistance helped patients taking HIV or oncology medicines with more than $1,600 toward their out-of-pocket costs in 2019, and helped patients taking multiple sclerosis (MS) medicines with more than $2,200 toward their out-of-pocket costs.[11] Despite HHS's assertions in the 2021 NBPP Final Rule that "we believe the impact to consumers will be minimal if issuers choose to continue their current behavior"[12] a national survey conducted by the National Hemophilia Foundation found that 72% of survey respondents believed that many patients would no longer be able to afford their medications if cost-sharing assistance was not permitted to be applied to annual out-of-pocket limits.[13]

---

[8] HHS Notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. at 29261 (codified at 45 C.F.R. § 156.130(h)).

[9] We have discussed our opposition to accumulator adjustment programs at length in both our comment letter on the 2021 NBPP proposed rule and our comment letter on the Medicaid Value-Based Purchasing proposed rule (85 Fed. Reg. 37286 (June 19, 2020)). When a health plan uses an accumulator adjustment program, it jeopardizes patients' ability to access needed medications, particularly when there may be no alternative options. This disruption can reduce adherence and increase abandonment, exacerbating underlying health conditions and leading to worse outcomes. Accumulator adjustment programs hurt enrollees, and HHS should not permit or encourage them.

[10] Congressman Rodney Davis. Davis, McEachin Introduce Bipartisan Legislation to Prevent Increased Prescription Drug Costs. November 2021. https://rodneydavis.house.gov/posts/davis-mceachin-introduce-bipartisan-legislation-to-prevent-increased-prescription-drug-costs

[11] PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost sharing-for-Brand-Medicines.pdf.

[12] 85 Fed. Reg. at 29232 (May 14, 2020).

[13] National Hemophilia Foundation. Americans Believe Government Should Require Copay Assistance Be Applied to Out-of-pocket Costs. October 15, 2020. https://www.hemophilia.org/news/americans-believe-government-should-require-copay-assistance-be-applied-to-out-of-pocket-costs

The 2021 NBPP final rule represented a complete reversal of final regulatory action taken by HHS in its 2020 NBPP final rule. Additionally, the 2021 NBPP final rule is not consistent with the statutory or regulatory definition of cost sharing because federal law requires that amounts charged as deductibles, coinsurance, or copayments under a health plan count toward the plan's annual limitation on cost sharing, without limiting the sources of funds that may be used to pay those amounts.[14] HHS failed to explain how it can simply "interpret" cost-sharing not to include cost-sharing assistance, in light of the existing statute and regulation, as well as the fact that the interpretation would not apply to many other types of patient assistance or financing mechanisms that similarly eliminate, reduce, or delay patient out-of-pocket spending for covered services.

Conversely, the 2020 NBPP final rule required plans to count toward the annual limitation on cost sharing amounts paid using manufacturer cost-sharing assistance for drugs that lack medically appropriate generic equivalents, protecting patients from facing significant, unexpected bills for drugs without alternatives as a result of plans implementing accumulator adjustment programs.[15] The abrupt reversal of the balance struck in the 2020 NBPP final rule was not adequately addressed by HHS in the 2021 NBPP final rule, and it directly contradicts the agency's prior determination that the potential for market distortion does not exist when manufacturers provide cost-sharing assistance for medicines without a generic equivalent.[16] We maintain that an incorrect interpretation of 18-year-old Internal Revenue Service (IRS) guidance related to *discount cards*, which differ in meaningful ways from manufacturer cost-sharing assistance, is the sole justification offered for this policy shift – a shift that could dramatically erode patient access to critical medicines.[17]

When accumulator adjustment programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious and chronic illnesses. Several states have taken steps to ban or limit use of accumulator adjustment programs by state-regulated plans.[18] HHS itself, in its recently finalized Medicaid rule, acknowledges "situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan" due to accumulator adjustment programs not applying the value of the manufacturer-sponsored assistance to the patient's deductible.[19] Further, HHS notes that "when this happens, the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for

[14] Patient Protection and Affordable Care Act § 1302(c)(3), 42 U.S.C. § 18022(c)(3); 45 C.F.R. § 155.20.
[15] 84 Fed. Reg. 17454, 17544-46 (Apr. 25, 2019).
[16] In 2017, less than one percent of all commercial market medicine claims were filled with cost-sharing assistance for a branded medicine where a generic equivalent was available. *See*, IQVIA. An evaluation of co-pay card utilization in brands after generic launch. February 2018. https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.
[17] 84 Fed. Reg. 29233 (May 14, 2020). See PhRMA's comment letter on the HHS Notice of Benefit and Payment Parameters for 2021. March 2, 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2021-NBPP-Comment-Letter_FINAL.pdf
[18] To date, the following states have banned accumulator adjustment programs: AR, AZ, CT, GA, IL, KY, LA, NC, OK, TN, VA, WV.
[19] Final Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-F) from the Department of Health and Human Services, Centers for Medicare & Medicaid Services will be published in the Federal Register on 12/31/2020. https://public-inspection.federalregister.gov/2020-28567.pdf.

those patients with rare and life threatening conditions."[20] Thus, accumulator adjustment programs can undermine medication adherence, which can lead to negative health outcomes for patients and increase overall health care costs.[21] Accordingly, we urge HHS to protect patients by reinstating the requirement from the 2020 NBPP final rule that plans must count manufacturer cost-sharing assistance toward the annual limitation on cost sharing for drugs that do not have a medically appropriate generic equivalent available.[22]

In addition to accumulator adjustment programs, industry experts and commentators have noted that health plans and pharmacy benefit managers (PBMs) may be using "copay maximizer programs," which subject certain patients to atypically high cost sharing based on their medical need for a medicine for which manufacturer cost-sharing assistance is available.[23] Growing use of these programs and their potential impact on certain patients, based solely on a medical condition or need for a specific medicine, is concerning in the best case and, per our comments below, could run afoul of nondiscrimination requirements. In a survey of commercial health plans conducted by MMIT in 2020, 23 percent of commercial enrollees were enrolled in plans where the plan sponsor had adopted a copay maximizer program for at least one medicine, and this number is expected to grow.[24] HHS should monitor use of these programs and their impact on patients.

If HHS is not willing to address accumulator adjustment programs at this time as part of the 2023 NBPP, at a minimum, HHS should require plans to include prominent, plain language to disclose the use of accumulator adjustment programs to prospective enrollees and in the annual summary of benefits and coverage, including an explanation for what that means for patients as they progress through their benefit and/or reach their deductible or out-of-pocket maximum. PhRMA also requests that HHS require health insurance issuers and QHP issuers offering the standardized plans proposed in this year's rule to count toward deductibles and the annual limitation on cost sharing amounts paid using manufacturer cost-sharing assistance for drugs that lack medically appropriate generic equivalents. Given that these plans are designed to be patient-friendly and equitable, PhRMA believes that they should not be allowed to utilize accumulator adjustment programs, which could undermine many of the stated-HHS goals of standardized plans for enrollees.

---

[20] Ibid.
[21] PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.
[22] For a more detailed discussion, please see our comment letter on the Notice of Benefit and Payment Parameters for 2021.
[23] TrialCard. Co-Pay Accumulators & Maximizers: Your Questions Answered, PT. 3. July 27, 2020. https://corp.trialcard.com/co-pay-accumulators-maximizers-your-questions-answered-pt-3/; Drug Channels. Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support. May19, 2020. https://www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html#:~:text=Under%20a%20copay%20maximizer%2C%20the%20full%20value%20of,it%20reduces%20or%20eliminates%20the%20patient%E2%80%99s%20out-of-pocket%20obligations.
[24] MMIT. Survey Shows That Copay Accumulators and Maximizers Continue to Be Popular. February 1, 2020. https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/survey-shows-that-copay-accumulators-and-maximizers-continue-to-be-popular/

Health Equity and Nondiscrimination

PhRMA commends HHS for its focus on advancing health equity for consumers purchasing Exchange coverage. This theme is present throughout much of the proposed rule, including the proposed changes to nondiscrimination provisions and discussions regarding advancing health equity through QHP certification standards. Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment.[25] We support the Administration's interest in advancing health equity, particularly in programs that are administered or supported by the Federal government, and providing best practice models for the private market.[26] The COVID-19 pandemic has had a disproportionately negative impact on diverse and underserved communities due to factors such as inequitable access to health care, a shortage of racially/ethnically diverse health care workers, the racial wealth gap, increased rates of living in crowded housing, and systemic racism.[27] The COVID-19 pandemic's disproportionate impact on Black and Brown communities clearly demonstrates that we can no longer wait to fix inequities in our health care system. PhRMA has supported – and looks forward to supporting – the Federal government in these important efforts.

PhRMA supports reducing health insurance barriers to facilitate equal access to prescribed medicines, along with policies and practices to help drive durable, systemic change such as improving clinical trial diversity; building a diverse health care workforce; and promoting best practices to improve equity in health care screening, diagnosis, and treatment. In addition, addressing social determinants of health (SDOH) – including disparities in income, patient costs, and barriers to access to care that are specific to a given community – is key to advancing health equity.

Last year, PhRMA conducted focus groups to understand the overarching factors inhibiting health equity. Focus group members expressed that addressing systemic racism and bias are among the most fundamental challenges to reducing disparities. Recent research among a nationally representative cohort of Americans found that 32 percent of Black Americans, 20 percent of Latino Americans, and 23 percent of Native Americans stated they had been discriminated against when seeking health care because of their race or ethnicity.[28] In addition, multiple studies have revealed that discrimination is associated with increased incidence of

[25] PhRMA, "Building a Better Health Care System: PhRMA's Patient-Centered Agenda" (available at: https://phrma.org/patients/building-a-better-health-care-system-phrmas-patient-centered-agenda)
[26] Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Order 13958. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/
[27] Health Equity Considerations and Racial and Ethnic Minority Groups. Centers for Disease Control and Prevention. Updated November 30, 2021. https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html
[28] Discrimination in America: Final Summary. Robert Wood Johnson Foundation. Jan 2018. https://www.rwjf.org/en/library/research/2017/10/discrimination-in-america--experiences-and-views.html

mental health disorders,[29,30] hypertension,[31] and all-cause mortality.[32] This evidence and the expressed challenges faced by focus group members demonstrate the harms of discrimination, a key social determinant, on health and health outcomes. In addition, focus group members expressed that authentic engagement with communities is critical to solving health inequities, as well as addressing discrimination and racism in health care.

PhRMA is taking action to address these unacceptable and pervasive findings by supporting policies to reduce health insurance barriers that currently impede equal access to prescribed medicines, along with policies and practices to help drive durable, systemic change such as improving clinical trial diversity. We support taking steps to build a more diverse health care workforce; and promoting best practices to improve equity in health care screening, diagnosis, and treatment.

Currently, many of the sickest patients and lower-income communities are burdened with a disproportionate share of health care costs. Through an endless web of high deductibles, rising cost sharing for some medicines, coverage exclusions, and narrow formularies, health insurance benefit design is increasingly standing between patients and the care they need. Moreover, we are concerned that individuals who could benefit significantly from robust health care coverage may not be enrolling in plans that best fit their needs due to a lack of health literacy or limited resources to identify the most appropriate coverage, such as a lack of internet access, transportation, or paid time off. For example, consumers may choose bronze-level plans based on lower premiums but with markedly higher cost sharing for the items and services they need; or they may forgo coverage entirely, without fully understanding the availability of premium subsidies and cost-sharing reductions (CSRs) for silver-level plans. Some consumers may actually be better off financially with slightly higher premiums and lower cost-sharing amounts, which could improve medicine adherence and health outcomes.[33] Research conducted after passage of the American Rescue Plan Act (ARPA) found that millions of people are now eligible for zero-premium silver plans with CSRs that limit deductibles to less than $200.[34] As discussed in comments above, PhRMA encourages HHS to conduct robust education efforts to improve health literacy and help consumers understand and use all of the tools available for purchasing appropriate health coverage.

---

[29] Gee GC, Spencer M, Chen J, Yip T, Takeuchi DT. 2007. The association between self-reported racial discrimination and 12-month DSM-IV mental disorders among Asian Americans nationwide. Soc. Sci. Med. 1982 63: 1984-96

[30] Pilver CE, Desai R, Kasl S, Levy BR. 2011. Lifetime discrimination associated with greater likelihood of premenstrual dysphoric disorder. J. Women's Health 2002 20: 923-31

[31] Dolezsar CM, McGrath JJ, Herzig AJ, Miller SB. 2014. Perceived racial discrimination and hypertension: a comprehensive systemic review. Health Psychol. 33: 20-34

[32] Farmer H, Wray L, Thomas J, Race and Everyday Discrimination on Mortality Risk in the Health and Retirement Study, Innovation in Aging, Volume 2, Issue suppl_1, November 2018, Page 649, https://doi.org/10.1093/geroni/igy023.2421

[33] PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.

[34] Matthew Rae, et. al., "How the American Rescue Plan Act Affects Subsidies for Marketplace Shoppers and People Who Are Uninsured," Kaiser Family Foundation, March 2021, https://www.kff.org/health-reform/issue-brief/how-the-american-rescue-plan-act-affects-subsidies-for-marketplace-shoppers-and-people-who-are-uninsured/

Standardized Plans (§ 156.201)

PhRMA supports HHS's proposal to require QHP insurers on FFEs and SBE-FPs to offer standardized health plans beginning in 2023. Ten state-based Exchanges (SBEs) and one SBE-FP already require QHP insurers to offer some version of standardized plans, simplifying the Exchange shopping experience and prioritizing benefit features that reduce out-of-pocket costs for key services.

Standardized plans can simplify health insurance enrollment in FFE and SBE-FP states by streamlining plan choices and making the shopping experience more patient friendly. Standardized plans contribute to these goals by providing plan options from different insurers with identical cost sharing, allowing shoppers to focus on important differences regarding plan premiums, coverage, provider networks, and quality.

Standardized plans can include lower cost sharing than non-standardized plans on specific services and designate some services eligible for coverage pre-deductible, increasing access to care for patients. As insurance coverage has eroded in the individual market in recent years, due in large part to rising deductibles and coinsurance, standardized plans would help ensure that insurers offer plans on Exchanges with predictable and more affordable cost sharing on needed care.

Cost Sharing Across Metal Levels. In FFE states, patients may have hundreds of plan options at each AV level, leading to confusion as they seek coverage. Nearly 75% of Exchange enrollees had more than 60 plan options to choose from in 2021.[35] Additionally, Exchange enrollees tend to be sensitive to price differences; they often seek plans with the lowest premiums.[36] This may lead shoppers to choose plans with high cost sharing that they only become aware of when they need care. The use of standardized plans aligns more features of a plan, such as provider networks and formularies, allowing patients to make easier side-by-side comparisons when choosing among variables.

Standardized plans improve patient health plan choices by emphasizing networks, providers, and quality of plans, instead of choices based solely on cost sharing differences between metal levels. As outlined in an issue brief released by the HHS Office of Health Policy, standardized plans have the potential to reduce discrimination and market segmentation by standardizing cost-sharing structures for certain services.[37] A 2016 study of 45 plans offered through SBEs with varying standardized plan policies showed that plan standardization appeared to eliminate adverse tiering and led to significant financial savings for those taking HIV drugs, with no significant difference in premiums.[38] Another study completed in 2016 found that silver

[35] Assistant Secretary for Planning and Evaluation (ASPE). Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces. December 2021. https://aspe.hhs.gov/sites/default/files/documents/222751d8ae7f56738f2f4128d819846b/Standardized-Plans-in-Health-Insurance-Marketplaces.pdf

[36] Gavel, Doug. "Up and out: Price Sensitivity in Health Care Insurance Market." Harvard Kennedy School, May 4, 2017. https://www.hks.harvard.edu/research-insights/policy-topics/health/price-sensitivity-health-care.

[37] ASPE, Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces. December 2021.

[38] Jacobs D. CMS' Standardized Plan Option Could Reduce Discrimination. Health Affairs Blog. Jan. 2016. https://www.healthaffairs.org/do/10.1377/hblog20160106.052546/full/

standardized plans covering certain services before the deductible had comparable premiums to non-standardized silver plan premiums.[39]

As we have noted previously, cost-sharing obligations can be a barrier to accessing health care services. According to one survey, one-third of Americans with private health insurance report postponing medical treatment because of cost.[40] This number jumps to more than half for low-income families with chronic conditions.[41] Many who receive care struggle to pay their cost-sharing charges, leading to financial insecurity and medical debt.[42] Critically, silver plan cost sharing on the Exchanges remains high. In a 2020 analysis of Exchange benefit designs in standardized versus non-standardized plans in 6 states that offer standardized plans, standardized silver plans had higher average combined maximum out-of-pocket (OOP) costs ($7,584) than non-standardized silver plans ($6,378), but lower deductibles (an average $1,509 combined deductible in standardized plans versus $3,379 in non-standardized plans).[43] PhRMA encourages HHS to consider ways to help patients overcome affordability and access challenges that are present in both standardized and non-standardized plans, including increased consumer education efforts around the availability of premium subsidies and CSRs, discussed further in our comments below. Outreach efforts should also include awareness of free preventive services and screenings which are necessary to deliver the services which can avoid and forestall health declines.

Additionally, standardized plans may offer more predictable prescription drug tiers. In recent years, Exchange plans in standardized plan states offered only 3 or 4-tier formularies, while more than a quarter of plans in FFE states that did not offer standardized options included 5 or more tiers.[44,45] Increased formulary tiering can lead to higher cost sharing (e.g., copayments or coinsurance) for patients as cost sharing varies by tier for preferred, non-preferred, and specialty drugs.

Copayments, Coinsurance, and Pre-Deductible Coverage. PhRMA supports the Administration's decision to utilize copayments, rather than coinsurance, for all prescription drug tiers. As we have noted in previous instances, the use of coinsurance can leave patients with unpredictable and unexpected out-of-pocket costs at the pharmacy counter – essentially a surprise medical bill – which may then lead to abandoned prescriptions, poor adherence, and worse health outcomes. In 2019, more than 64% of commercially insured patients did not fill

---

[39] Federal Standardized Health Insurance Plans Could Improve Access to Care without Raising Premiums. Milliman and Families USA. June 2016. https://www.familiesusa.org/resources/federal-standardized-health-insurance-plans-couldhelp-improve-access-to-care-without-raising-premiums/

[40] Riffkin, R. Cost Still a Barrier Between Americans and Medical Care. Washington: Gallup, Nov. 28, 2014. http://www.gallup.com/poll/179774/cost-barrier-americans-medical-care.aspx. Accessed Jan. 2017

[41] Galbraith, A. Nearly Half of Families in High-Deductible Health Plans Whose Members Have Chronic Conditions Face Substantial Financial Burden. Health Affairs 20.2 (2011): 322-331.

[42] Hamel, L et. al. The Burden of Medical Debt: Results from the Kaiser Family Foundation/New York Times Medical Bill Survey. Menlo Park: Kaiser Family Foundation, Jan. 6, 2016.

[43] Avalere Health. Differences in 2020 Exchange Benefit Design for Standard Versus Non-Standard Plans. December 2020.

[44] Avalere Health. Avalere analysis of 2020 Benefit and Cost Sharing Exchange Public Use File and plan benefit design data from CoveredCA andAccess Health CT. October 2020.

[45] *See* Covered CA 2021 plan designs; DC Health Exchange 2021 plan design summary; MA Health Connector 2021 standardized plan designs; NY State of Health 2021 Standard Cost Sharing Chart; Oregon Health Insurance marketplace 2021 standard plan designs; Vermont Health Connect 2021 plan designs; Washington State Cascade Care 2021 Standard Plan Designs

their new prescription when OOP costs exceeded $250, while less than 14% of patients abandoned their prescriptions when OOP costs were under $30.[46] The use of fixed dollar copays places a limit on the maximum amount a patient will be asked to pay per prescription, per month and/or annually, leading to more predictable costs and better treatment adherence.[47] Coinsurance can be confusing to patients and makes it difficult for them to anticipate or predict actual OOP costs when deciding to seek care. Including standardized plans in FFE and SBE-FP states that impose affordable copays rather than coinsurance could improve adherence, lead to better outcomes, and increase patient satisfaction with their plans.

Standardized plan usage in FFE and SBE-FP states provides HHS the opportunity to prioritize improving patient access to life-saving medications. Researchers have found plans in states with standardized benefit designs covered more branded drugs for conditions including HIV, multiple sclerosis (MS), and cancer without utilization management than in states without standardized plan requirements .[48] Eight SBEs using standardized plans require only copayments to access generic drugs before the deductible, though cost sharing varies by state for preferred brand drugs, non-preferred brand drugs, and specialty drugs with copayments or coinsurance before or after the deductible.[49]

Research has also shown that standardized plans used separate deductibles more often than non-standard plans.[50] It is important to note that some conditions are primarily treated by prescription drugs, leading to a disadvantage in the use of combined deductibles for patients who do not have other medical costs to meet their deductibles. The use of separate drug deductibles in standardized plans may allow patients to meet the (typically, lower) drug deductible earlier in the year than in plans with combined medical and drug deductibles. This allows some patients quicker access to their plan's cost-sharing requirements to get access to their prescriptions. Four states with standardized plan requirements have separate drug deductibles for at least some of their metal levels.[51] These states allow patients to pay just the cost sharing after meeting the separate drug deductibles, which are significantly lower than the medical deductibles.

For the future, we encourage HHS to consider a separate drug deductible design for standard silver and silver 73 CSR plans. Although the proposed silver plan designs, which offer copayments across all drug tiers, are a significant improvement over plans currently offered, the proposed combined deductibles of $5,800 and $5,700, respectively, could jeopardize patient access to critical medicines. Optimizing silver plan design is essential since they have the potential to impact the greatest number of patients, accounting for over half of all covered lives

---

[46] IQVIA. Medicine Spending and Affordability in the U.S. August 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us

[47] PhRMA. Making Medicines More Affordable for Commercially Insured Patients and Medicare Beneficiaries. 2021. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Industry-Profile-2021/Making-Medicines-More-Affordable-for-Commercially-Insured-Patients-and-Medicare-Beneficiaries-2.pdf

[48] Avalere Health. "Analyses of Standard Plans: Formulary Placement and Plan Benefit Design". November 2020.

[49] ASPE, December 2021.

[50] Avalere Health. "Analyses of Standard Plans: Formulary Placement and Plan Benefit Design". November 2020.

[51] ASPE, December 2021

in Exchange plans (55 percent).[52] Higher AV requirements also offer greater design flexibility than bronze plans. Finally, the proposed gold and platinum plans include pre-deductible coverage across all drug tiers, therefore, separate deductibles are unnecessary.

Standardization to Facilitate Exchange Shopping. HHS has noted that patients may have difficulty navigating the "complex tradeoffs among cost sharing differences among a large number of plans."[53] As discussed above, without standardization across plans, patients often purchase plans primarily based on premiums and do not focus on cost-sharing parameters while shopping. Requiring insurers to offer at least some standardized plans on the FFE and SBE-FPs can simplify the process of patients choosing health insurance coverage by streamlining plan choices in a patient-friendly manner. This is especially true when the standardized plan contains patient-friendly cost-sharing parameters such as low deductibles and fixed-dollar copayments. Additionally, patients may lack health insurance literacy and knowledge of how to pick a plan when Exchanges offer so many options. For patients with high health needs, such as those with chronic conditions, the differences between plans could mean significantly higher—or lower—out-of-pocket costs.

In 2021, there were more than 5.4 million Exchange enrollees receiving CSRs. Individuals with income at 200-250% of the federal poverty level are eligible for CSRs on silver plans, but they may find that the relatively modest benefits are not worth the added cost of purchasing a silver plan instead of a lower-cost bronze plan. In some cases, bronze cost sharing may also be too high for individuals. The additional $10.2 million awarded in funding to current Navigator grantees in FFE states was a respectable step toward educating patients on subsidies and the tools that exist to assist them in calculating their possible OOP costs; however, additional work still needs to be done to assist patients in enrolling in plans that are affordable when factoring in OOP costs. We urge HHS to continue prioritizing ways to assist patients with estimating total OOP costs under various plan options within the HealthCare.gov platform.

Standardized Plan Display. States that currently offer standardized plans have used preferential display of these plans on their Exchange sites. In Connecticut, Washington DC, Massachusetts, and Oregon, plans must be labeled with a "standard" label, while other states differentiate plans in their own ways.[54] Differentiating standardized plan options may lead to more appropriate plan choices based on the different needs of patients. PhRMA applauds these decisions from current SBE states and encourages HHS to include preferential display for standardized plans in FFE and SBE-FP states.

Standardized Plans and Health Equity. The proposed rule includes numerous rationales for reinstituting standardized options for plan year 2023, including "combatting discriminatory

---

[52] Kaiser Family Foundation. Marketplace Plan Selections by Metal level: Open Enrollment 2021. https://www.kff.org/health-reform/state-indicator/marketplace-plan-selections-by-metal-level-2/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[53] HHS Notice of Benefit and Payment Parameters for 2017, 80 FR 75487

[54] Assistant Secretary for Planning and Evaluation (ASPE). Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces. December 2021. https://aspe.hhs.gov/sites/default/files/documents/222751d8ae7f56738f2f4128d819846b/Standardized-Plans-in-Health-Insurance-Marketplaces.pdf

benefit designs that disproportionately impact disadvantaged populations" and "advancing health equity."[55] PhRMA agrees with HHS that standardized plan options should be viewed as one of many tools to advance health equity, because standardized options may help individuals more easily identify plans that may potentially have benefit designs that discriminate against individuals with certain disabilities or health conditions.

PhRMA urges HHS to consider the following suggestions for advancing health equity through standardized plan design. These suggestions encompass both the process of developing future standardized plans designs and the components that should be contemplated within those plans.

1. **Broad stakeholder input should be sought during plan design.** Seeking input from a broad group of stakeholders, including patient advocates and health care providers, will help ensure that the final standardized plan design meets the needs of patients, improves health equity, and can be implemented and administered in a patient-friendly manner. To ensure that standardized plans advance health equity, the communities that are disproportionately experiencing health disparities should be included in the process. These groups are often underrepresented in engagement efforts. Community-based stakeholders understand the specific needs of communities, which is crucial for successfully designing and implementing outreach efforts to engage the underserved. HHS should examine qualitative, as well as quantitative, data.
2. **Plan designs should seek to reduce disparities within health conditions that disproportionately impact disadvantaged communities.** Plan designs should prioritize making medicines and other health care services equitably accessible for all communities, particularly those of color and who are disadvantaged. HHS can make progress by evaluating out-of-pocket spending and cost sharing for treatments for conditions that disproportionately affect communities of color to understand and address insurance related access barriers.[56] One option to address any identified access barriers is to ensure that select services that can reduce health disparities are made available at minimal or no cost sharing. Additionally, standardized plans should be designed to prohibit insurers from engaging in adverse tiering as discussed elsewhere in these comments.
3. **Plan designs must acknowledge and should be designed to counteract systemic racism wherever possible.** Standardized plan designs should be constructed to tackle racial and health inequities. HHS should identify polices, practices, and procedures imbedded in the U.S. health care and health insurance system insurance that contribute to racial and health inequities, and begin to replace them with policies, practices and procedures that address systemic racism. As a first step, standardized plans must ensure that health care algorithms are based on rules and data sets that accurately reflect the relevant patient population and are not discriminatory against communities of color. Beyond algorithms, additional tools should be developed and utilized to safeguard against discriminatory practices in order to better protect against racial inequities. In addition,

[55] 87 Fed. Reg. 584, 673 (Jan. 5, 2022)
[56] PhRMA's Medicines in Development. 2021 Report: Health Equity. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/MID-Reports/MID-Health-Equity-2021-Report.pdf

network adequacy requirements can be implemented to focus on specialists that treat conditions that are disproportionately prevalent in communities of color, ensure that these specialists are covered adequately in-network, and take into consideration the need for culturally appropriate providers. PhRMA appreciates that HHS proposes to implement time and distance standards in network adequacy reviews for QHPs. PhRMA also urges HHS to analyze data that reflect SDOH, such as transportation access, when developing network adequacy requirements given the impact on access, adherence, and health outcomes.[57]

4. **Data collection, analysis and reporting should be a priority so that data-driven decisions can be made.** Expanded data collection and reporting will be integral to obtaining accurate information to enable appropriate decisions. Health equity-related goals must be identified to determine necessary baseline data as well as metrics used to understand if health disparities are being addressed as planned. Granular race and ethnicity data, as well as better data on sexual orientation and gender identity will be needed to help determine whether particular plan designs are advancing or harming health equity.[58] Equally important is the collection of data regarding SDOH, such as income, access to reliable transportation, and the ability to take time away from work. Data on these measures currently are not reflected in claims data but must be considered when designing standardized plans to promote health equity. Engaging the patient community, safeguarding patient privacy, and ensuring that data is used to improve and provide the best care possible without stigmatization is essential at the outset and through the entirety of any data collection initiative.
5. **The AV Calculator should not impede health equity efforts.** Under current practices, the AV calculator, which is used to estimate the AV of a plan and place it in a tier, is flawed as a tool to advance health equity. For example, the claims data used to develop cost estimates may not be appropriately representative of all patient sub-populations, because, for example, it is not adjusted to account for unmet need. Given the disparities that exist in health care access,[59] and the role that cost sharing can play in that access, HHS should examine how the AV calculator can be improved to have greater sensitivity to pervasive health care inequities. Additionally, the standard population method currently used generalizes calculations for the entire United States broadly, meaning regional population differences are not accounted for.

SBE adoption of standardized plans. The proposal to require QHPs on the FFE and SBE-FPs to offer standardized options should be implemented as proposed, which would result in a majority of consumers having access to standardized plans. As HHS notes, many SBEs have existing standardized plan requirements that have resulted in the availability of plans with more

[57] Syed S, Gerber B, Sharp L. Traveling towards disease: transportation barriers to health care access. J Community Health. 2013;38(5):976–93.
[58] *See* "Gaps in Available Data Exacerbate Health Disparities and Create Barriers to Change," PhRMA, January 2021 and "Disparities in Data: Solutions and Barriers to Implementation," PhRMA, September 2021.
[59] Xie Z, St Clair P, Goldman DP, Joyce G. Racial and ethnic disparities in medication adherence among privately insured patients in the United States. PLoS One. 2019;14(2):e0212117.

affordable cost sharing than non-standardized plans.[60] PhRMA encourages HHS to assist states with SBEs that have not yet been able to implement standardized plans because they can be an important tool for patient access and health equity. Designing plans that address the needs and concerns of a particular state or population requires access to and analysis of actionable data. PhRMA has identified several barriers to data analysis[61] as it relates to standardized plan development and encourages HHS to engage with states to address these barriers as it continues to advance policies on standardized health plans and health equity:

1. In addition to the design improvements discussed above related to health equity, tight timelines related to the release of the AV calculator make it more difficult for SBEs to design data-driven plans. Although states can work with a draft version of the AV calculator, delays to AV calculator updates can make it difficult for states to analyze their data and finalize plans.
2. Many states have limited bandwidth for performing more advanced data analysis; this is especially challenging for smaller states. An Urban Institute paper revealed that even if insurers provided regular reports, Exchange officials believed they would still struggle with analysis due to insufficient staff resources.[62] Quantitative analysis is typically limited to what is provided by actuaries who support state staff.[63] In addition, many states do not have actuaries on staff. To overcome these challenges, states often must contract with an actuary in order to access the needed expertise.
3. Differences in how data are reported to states make it more difficult for them to make comparisons, interpret data, and conduct data analysis. For instance, when carriers submit data using Excel files, it is not always in a consistent format and may have varying levels of detail that make it more difficult for states to interpret the reasons for differences across carriers. One solution could be to have standardized plan templates for data requests to facilitate subsequent analysis.

Essential Health Benefits

The ACA's nondiscrimination protections are particularly important in the context of prescription drugs, given the potential for insurer gaming based on a known need for specific medicines – often year after year – in the case of patients with certain health conditions. Comprehensive prescription drug coverage—whether for medicines covered by the outpatient pharmacy benefit or as part of the medical benefit, such as drugs administered incident to a

[60] Avalere Health. Differences in 2020 Exchange Benefit Design for Standard Versus Non-Standard Plans. December 2020.
[61] In addition to data analysis, challenges to data collection pose significant barriers to standardized plan development and health equity in general. Improvements to collection and dissemination of consumer experience, REL, and SDOH data are essential to improving health equity, and PhRMA urges HHS to work with other federal agencies to implement solutions. *See* "Gaps in Available Data Exacerbate Health Disparities and Create Barriers to Change," PhRMA, January 2021 and Disparities in Data: Solutions and Barriers to Implementation, PhRMA, September 2021.
[62] Urban Institute. State Efforts to Lower Cost sharing Barriers to Health Care for the Privately Insured. June 2017. https://www.urban.org/sites/default/files/publication/90961/2001311-state-efforts-to-lower-cost sharing-barriers-to-health-care-for-the-privately-insured.pdf
[63] Consumers for Quality Care, Standardized Plans in Individual market Health Insurance. March 2021. https://consumers4qualitycare.org/wp-content/uploads/2021/03/Standardized-Plan-Guide-3.1.pdf

physician's service—is integral to preventing, treating, and curing serious and chronic medical conditions, as well as improving quality of life and reducing other health care costs. That is why PhRMA has long supported HHS's efforts to further define and enforce nondiscrimination principles through EHB and other authorities.

Provision of Essential Health Benefits (§ 156.115). PhRMA supports HHS's proposal to remove from its regulations the flexibility currently afforded states to permit health insurance issuers to substitute benefits between EHB categories. As HHS notes, it appears that no state has ever exercised this flexibility, likely because permitting such cross-category substitution could harm patients, especially those living with chronic conditions and disabilities. In addition, this type of flexibility in providing EHBs would make it unnecessarily difficult for state and federal regulators to ensure that health insurance issuers are actually covering the EHBs they are required to provide. We therefore agree with removing authorization of cross-category substitution.

Refine EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125). PhRMA applauds HHS's proposal to refine the benefit design nondiscrimination standard under EHB requirements. Health plan benefit designs – especially in the individual and small group market – can be used by plans to discriminate against or discourage enrollment by individuals with significant health care needs, including those with chronic conditions or disabilities, and other disadvantaged populations. Although, under current regulations, an issuer does not provide EHB if it discriminates based on: "an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions,"[64] this standard has proven insufficient at preventing plans from using benefit design flexibilities to discriminate against patients that rely on certain prescription drugs. Specifically, plans' use of discriminatory prescription drug formularies to discourage enrollment among certain populations has been well documented over the years.[65] For many patients with chronic conditions, plans may be able to discourage enrollment by certain higher cost individuals simply by not covering the medicines they need or placing them on a high formulary tier. However, researchers have also found that sophisticated plans have even restricted access to lower cost brand drugs and generics when demand for those drugs attracts patients who are more expensive for reasons other than their drug utilization (for example, expected use of medical services).[66]

Specifically, PhRMA supports HHS's proposal to require benefit design, including drug formulary tiering, to be "clinically based" and not based solely on the cost of items and services. We are optimistic this action will help ensure the benefit packages offered by plans required to cover EHBs do not discriminate against disadvantaged patients.

---

[64] See 45 CFR § 156.125(a).
[65] Douglas B. Jacobs, & Benjamin D. Sommers. "Using drugs to discriminate: adverse selection in the Insurance marketplace," 372 New Eng. J. Med. 399, 401 (2015).; Avalere Health. 2016 exchange plans improve access to medicines used to treat complex diseases, April 2016. http://avalere.com/expertise/managed-care/insights/2016-exchange-plans-improve-access-to-medicines-used-to-treat-complex-disea.
[66] Michael Geruso, Timothy J. Layton, and Daniel Prinz. Screening in contract design: evidence from the ACA health insurance exchanges. NBER Working Paper No. 22832, November 2016, Revised October 2017.

Presumptively Discriminatory Practices

Adverse Tiering. Formulary tiering can be an appropriate tool for health plans to use when several medically appropriate treatment regimens for a condition are available to patients. Adverse tiering – the practice of putting all or most drugs for a particular condition on the highest cost-sharing tier – is not a legitimate use of formulary tiering, because it cannot encourage use of a preferred drug.[67] It serves only to shift costs from insurers to patients—or to discourage patients with significant medical needs from enrolling in the first instance. Moreover, the resulting high cost sharing has the known, entirely foreseeable effect of discouraging sick patients from using needed medicines. HHS appropriately defines "adverse tiering" as a benefit design that is presumptively discriminatory.

HHS also discusses the discrimination implications of adverse tiering of prescription drugs used to treat chronic health conditions. HHS states that relying on a drug's cost alone is not a reasonable justification for discriminatory benefit design; moreover, plans providing EHB should not have adverse drug tiering that discourages individuals with substantial health care needs from enrolling. More than half of all adults in the US have been diagnosed with a chronic condition. Chronic conditions are more likely among adults enrolled in public insurance, adults in rural areas, and among certain communities of color.[68] Due to the health equity implications, PhRMA supports HHS taking action on adverse tiering that constitutes discrimination.

Labeling adverse tiering as presumptively discriminatory is consistent with Medicare's approach in Part D, as well as emerging state practices. The program requirements in Part D have fostered a competitive marketplace where beneficiaries have a choice of plans that have successfully controlled costs.[69] Part D's formulary standards include the following regarding tier placement:

> CMS will review tier placement to ensure that the formulary does not substantially discourage enrollment of certain beneficiaries… Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.[70]

This standard is a crucial patient protection and, while CMS could improve its enforcement of these best practices in Part D, overall this standard has helped improve access to medicines and helped prevent plans from using formulary tier placement to risk select. Given the lower coverage standard for EHB plans overall (one drug per category/class as opposed to Medicare's

---

[67] Placing certain formulations on the highest cost-sharing tier is also a concerning practice, as new formulations of approved drugs can offer significant advances in therapy.
[68] Boersma P, Black LI, Ward BW. "Prevalence of Multiple Chronic Conditions Among U.S. Adults." 2018. Preventing Chronic Disease 2020;17:200130. https://www.cdc.gov/pcd/issues/2020/20_0130.htm
[69] CBO Medicare baselines for 2004 through 2011 available at www.cbo.gov.
[70] Prescription Drug Benefit Manual, Chapter 6, Section 30.2.7.

two), formulary tiering reviews to prevent discriminatory design is a critical protection needed in plans providing EHB.

States have also begun to examine tier placement when assessing whether plans are discriminating against individuals with certain conditions.[71] For example, the Florida Office of Insurance Regulation provides a nondiscrimination safe harbor for HIV/AIDS drug coverage if a health plan's tiered formulary of HIV/AIDS medications is at least as favorable as the state's benchmark plan.[72] Citing concerns about patient access, Delaware legislators enacted a law that prohibits plans from placing all drugs in a given class on a specialty tier.[73] California law provides that:

> "[T]he federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs... [A]ssignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen."[74]

Colorado insurance regulators issued guidance in 2016 that identified "placement of most or all drugs that are used to treat a specific condition on the highest cost tiers as discrimination against those individuals who have chronic conditions that require treatment with such drugs."[75] The state subsequently codified anti-discriminatory plan design in regulations, which required health plans to offer plans with pre-deductible copays across all drug tiers.[76]

Formulary Exclusions. In addition to formulary tiering, HHS should consider formulary exclusions – which prevent patients from accessing a medicine without paying completely out of pocket or undertaking a burdensome appeals or exceptions process – to be presumptively discriminatory if there is not clinical support for the exclusion. In less than 10 years, the practice of formulary exclusions has grown to exclude nearly a thousand prescription medicines across the three largest PBMs' standard formularies. From 2014 to 2020, the number of medicines excluded by at least one of the three largest PBMs from their standard formularies increased by

---

[71] D. Cusano, "State Authority to Enforce Non-Discrimination Provisions Applicable to Individual and Small Group Market Coverage," Georgetown University Health Policy Institute, August 2015. https://georgetown.app.box.com/s/8h9hjg9h52esfjwhwfctb2scz5w88r6m

[72]Florida Office of Insurance Regulation, "Informational Guidance on Florida's Form and Rate Filing Process for Patient Protection and Affordable Care Act (PPACA) Compliant Products in the Small Group and Individual Markets," March 25, 2015.http://www.floir.com/siteDocuments/PPACANoticeToIndustry03242015.pdf

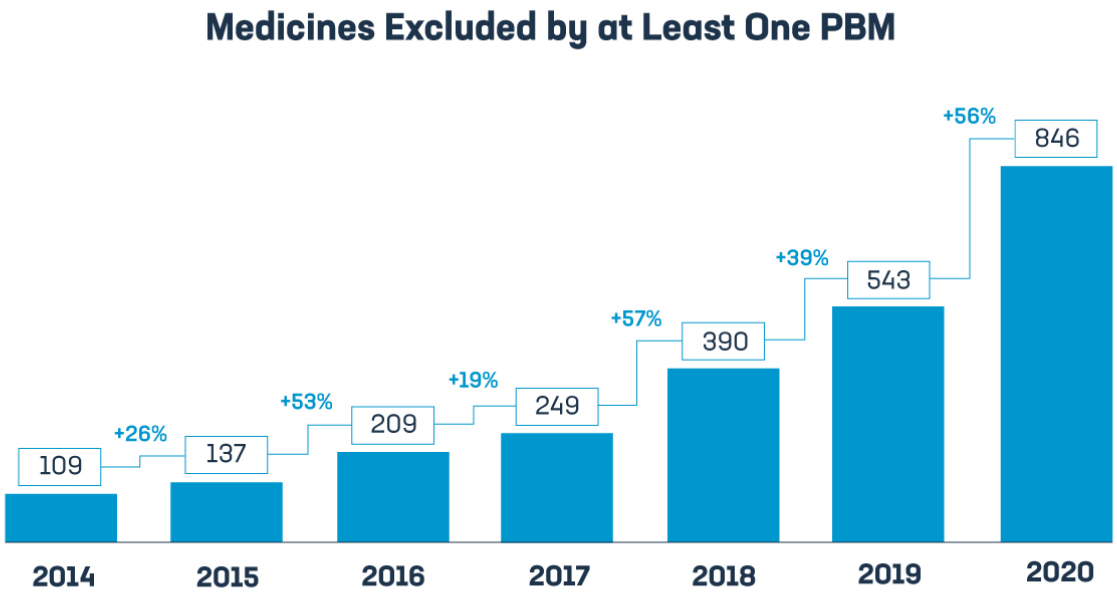
[73] 18 DE Code Section 3364; https://www.legis.delaware.gov/json/BillDetail/GetHtmlDocument?fileAttachmentId=46159

[74] California Health and Safety Code Section 1342.71

[75] Colorado Department of Regulatory Agencies, Division of Insurance, Bulletin No. B-4.82, Issued January 2015.

[76] Section 3 CCR 702-4-2-58-5 - Drug Tiering and Non-Discriminatory Plan Design

an average of 34% per year.[77] As a result of this practice, each year, hundreds of thousands of patients with commercial insurance face barriers accessing the treatments prescribed by their doctors. This is the case for both new prescriptions and for patients who have been stable on a medicine prior to the exclusion.



Source: Data shown in the figure above are based on a compilation of CVS Caremark's, Express Scripts' and OptumRx's formulary exclusion listings from 2014-2020.

If the EHB nondiscrimination provisions do not explicitly speak to formulary exclusions, health plans could attempt to restrict prescription drug coverage by leaving innovative medications off of formularies entirely (as a substitute for adverse tiering). For example, if the nondiscrimination provision is not adequately clarified and enforced, a plan could gain an advantage over its competitors by discouraging the enrollment of individuals with particular health care needs (and high health costs), by excluding coverage for some or many drugs within a specific class. Once one plan gains a competitive advantage by avoiding high-cost individuals or individuals with a disability, other plans might follow suit and reduce their benefits, with the result that certain persons with disabilities are effectively denied coverage that meets their needs. As discussed above, researchers document such strategic behavior by Exchange plans, with plans "designing formularies to be differentially unattractive to unprofitable groups." These formulary patterns "do not simply reflect insurers passing-through underlying drug costs to the consumer or nudging consumers toward lower-cost substitutes."[78]

[77] Xcenda. Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access. September 16, 2020. https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access
[78] Michael Geruso, Timothy J. Layton, and Daniel Prinz. Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges. NBER Working Paper No. 22832, November 2016, Revised October 2017.

The challenge of avoiding this race to the bottom will require drawing on best practices and lessons from state departments of insurance and Medicare Part D, both of which offer successful models for recognizing the essential role of medicines, protecting beneficiaries from discrimination, and promoting access to care, while maintaining affordability. As described above, in Part D, CMS added protections that exceeded statutory requirements in order to ensure a well-functioning market.

Similarly, states have begun to set standards for formulary breadth and to prevent discrimination as a part of their oversight of QHPs. All of these practices should be considered for adoption in federal regulation of the Exchanges to ensure broad protections of individuals vulnerable to discrimination.

Use of Accumulator Adjustment Programs. HHS should also classify use of accumulator adjustment programs by health plans (in situations where there is no generic equivalent) as presumptively discriminatory. Health plans and PBMs have adopted programs whereby, contrary to established practice, they exclude from the deductible or annual limit on cost sharing the value of cost sharing paid by enrollees, *but only when the enrollee uses manufacturer cost-sharing assistance to pay*.

When accumulator adjustment programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious and chronic illnesses. Thus, accumulator adjustment programs can undermine medication adherence, which can lead to negative health outcomes for patients and increase overall health care costs.[79] This discriminates against enrollees who use cost-sharing assistance provided by drug manufacturers by offering more limited benefits – and higher cost sharing – to them as compared to other enrollees who have other forms of cost-sharing assistance, including family support. There is no clinical basis for this disparate treatment. Indeed, it treats enrollees worse simply because they have significant health needs that require certain drugs; accumulator adjustment programs, especially applied in situations where there is no generic equivalent available,) should be considered presumptively discriminatory. In addition, HHS should carefully monitor all accumulator adjustment and copay maximizer programs (discussed in greater detail above) for nondiscrimination compliance.

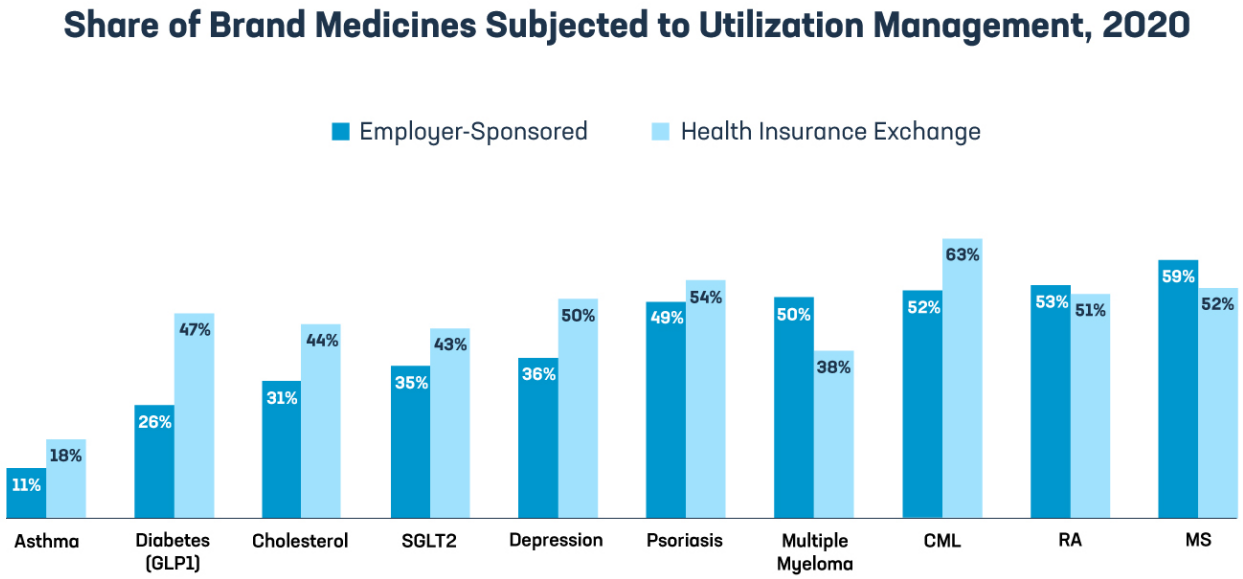
Utilization Management. As part of its investigation into discriminatory benefit design tools used by health plans, PhRMA recommends that HHS analyze the potential effects of utilization management (UM) (e.g., prior authorizations (PA), step therapy) on health disparities. In the commercial market, UM has increased for drugs across a wide array of therapeutic areas, including autoimmune disorders, asthma/allergies, cardiovascular disease, diabetes, and HIV.[80]

---

[79] PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.

[80] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf

All of these have higher rates of impact among minorities and populations of color. [81,82,83] Exchange plans are also more likely to impose UM requirements than employer plans, which could disproportionately impact QHP enrollees. [84]



Notes: Utilization management refers to medicines subjected to prior authorization and/or step therapy. MS: Multiple Sclerosis; RA: Rheumatoid Arthritis; CML: Chronic Myeloid Leukemia; MM: Multiple Myeloma. 'Cholesterol' includes dyslipidemic brand medicines. Source: Avalere PlanScape Analysis, January 2021.

A recent study published in *Health Affairs* found that more than half of step therapy policies developed by commercial health plans were more restrictive than recommended clinical guidelines, meaning patients and providers may have to overcome time-consuming hurdles imposed by health plans before a medicine is covered. The researchers concluded that "[t]hese findings raise questions about potentially overly restrictive step therapy protocols, as well as concerns that variability across health plans makes protocols onerous for patients and practitioners alike." Additionally, the consistency of step therapy protocols varied within and across plans. This raises important questions about the adequacy of the clinical rationale for certain protocols developed by health plans and the potential for health plan discrimination against certain populations, including patients who may have fewer resources to navigate unjustifiably burdensome protocols.[85] Stakeholders, including patient and provider organizations, have also raised concerns about the use of UM, including bipartisan Members of Congress who have co-sponsored the Safe Step Act to enact certain guardrails and patient protections around

[81] Impact on Racial and Ethnic Minorities, HIV.gov, https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities
[82] Minority Health, NIH: National Institute of Allergy and Infectious Diseases, https://www.niaid.nih.gov/research/minority-health
[83] HHS Office of Minority Health, Policy and Data, https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlID=4
[84] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf
[85] Lenahan, K. et al. Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans. November 2021. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00822

the use of step therapy.[86]

Given the proliferation of UM, especially in Exchange plans, systematic analysis of whether health plan-imposed administrative burdens and coverage restrictions disproportionately impact underserved or minority communities is necessary.

Application to Group Health Plans

While HHS's proposed clarification of the EHB nondiscrimination standard may apply only to plans required to cover the EHB package, we encourage HHS along with the Departments of the Treasury and Labor (the Departments) to evaluate the benefit designs that group health plans and their PBMs implement to identify practices – including formulary exclusions, adverse tiering, use of accumulator adjustment programs or copay maximizers, and step therapy – that may injure enrollees with significant health care needs. The Departments should reaffirm that there continues to be a "general rule that all prescription drugs covered by . . . a plan are considered [essential health benefits]."[87] This general rule, that all covered prescription drugs are considered EHBs for the purposes of the annual limitation on cost sharing, necessarily applies across the market, to effectively apply to all non-grandfathered health plans, encompassing not only all non-grandfathered individual and small group market health insurance coverage under Public Health Service Act § 2707(a), but also non-grandfathered group health plans – whether insured or self-insured, and whether small or large – under Public Health Service Act § 2707(b). The Departments should rely on section 2707 to examine group health plan practices, including accumulator adjustment programs and copay maximizers, that delay or deprive individuals with chronic conditions and other disadvantaged populations of the benefits of the ACA's annual limit on cost sharing. Further, the Departments should apply other statutory authorities, including section 1557 of the ACA and section 2705 of the Public Health Service Act to ensure that group health plans and their service providers, including PBMs, do not design or implement benefit designs that discriminate on the basis of health status, age, sex, race, ethnicity, national origin, or disability.

Oversight tools

Finally, we encourage HHS to expand the tools it uses to evaluate Exchange plans for compliance with the EHB nondiscrimination standard:

- A more effective federal oversight process, particularly in the HealthCare.gov states (with assurance/proof from SBEs that they are providing oversight) could lead to improved coverage of prescription medicines. Additionally, better tools, such as a robust formulary review tool as used in Part D, could reduce the variation from state to state and provide more thorough oversight.

[86] Safe Step Act, S.464, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/464/all-info.
[87] 2020 NBPP proposed rule, 84 Fed. Reg. 227, 320 (Jan. 24, 2019) (proposed to be codified at 45 C.F.R. § 156.130(h)(1)(iii) ("Notwithstanding the general rule that all prescription drugs covered by such a plan are considered EHB . . .")).

- The CMS formulary review suite includes a nondiscrimination clinical appropriateness tool that analyzes the availability of drugs associated with 10 conditions (bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, opioid use disorder, prostate cancer, rheumatoid arthritis, and schizophrenia). This list of classes has not been updated since the 2018 NBPP[88] and could be expanded to ensure more significant clinical review for other therapeutic areas.

- HHS conducts nondiscrimination reviews for Exchange plan formularies using a formulary outlier test that identifies plans that have an unusually large number of drugs with PA and step therapy. This outlier review focuses on 28 USP categories and classes.[89] Instead of using an outlier test, HHS could establish a set of predetermined nondiscrimination formulary standards to which plans will be held accountable. This set of standards would include global and class-specific thresholds tied to metrics, such as the proportion of drugs covered as preferred or the proportion available without utilization management.

- Nondiscrimination reviews could be further broadened to analyze whether certain populations (by income, race, geography, etc.) might be particularly impacted by inadequate or discriminatory formulary design.

Annual Eligibility Redeterminations (§ 155.335)

PhRMA supports changes that will take patients' OOP costs into account when determining the plan they are reenrolled in, in the event they do not actively select a plan that meets their needs during Open Enrollment. We believe these changes may lead to increased enrollment in plans with lower out-of-pocket costs for prescription drugs, increased adherence, and improved quality of life for patients.

We are concerned that many Exchange enrollees today are enrolled in plans that do not provide affordable cost sharing for brand medicines and understand that some of these enrollees may be eligible for CSRs that may enable them to enroll in better coverage. Therefore, we support changes to the annual eligibility redetermination process that would direct patients to consider more generous plans with CSRs if they are eligible, particularly when they may be enrolled in a bronze plan but could incur lower OOP costs on a silver plan because they qualify for CSRs. According to CMS data on the 2021 Open Enrollment period, 1.6 million individuals with income between 100% and 250% of FPL were enrolled in bronze plans in 2021 through HealthCare.gov; the vast majority of these individuals are likely eligible for CSRs.[90] For those individuals, even if they do have a small premium payment each month, they are often better off

[88] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program. 81 FR 94058 (December 22, 2016). https://www.federalregister.gov/documents/2016/12/22/2016-30433/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2018.
[89] Qualified health plan certification: information and guidance. review tools. https://www.qhpcertification.cms.gov/s/Review%20Tools.
[90] Centers for Medicare & Medicaid Services. 2021 OEP State, Metal Level, and Enrollment Status Public Use File (ZIP). April 21, 2021. https://www.cms.gov/research-statistics-data-systems/marketplace-products/2021-marketplace-open-enrollment-period-public-use-files

paying that small monthly premium for a silver CSR plan.[91] As we mention above, education and outreach are important to ensure enrollees understand this trade-off and the potential benefits of CSR plans. Together, these changes could lower OOP costs for many enrollees, which would allow improved access to medications and services for patients with low and moderate incomes.[92]

Additionally, HHS indicates that, under this proposal, a current bronze QHP enrollee could be automatically reenrolled into an available silver QHP with a lower net premium and higher plan generosity by the same issuer. At the end of Open Enrollment for 2021, more than 800,000 HealthCare.gov enrollees were in zero-premium bronze plans, and many of them would be better off in silver plans with the new ARPA subsidies.[93] HHS also considers reenrolling a silver QHP enrollee into another available silver QHP that may have lower annual OOP costs. PhRMA agrees with HHS that the inclusion of cost-sharing factors in annual redetermination eligibility guidelines would be beneficial for many Exchange enrollees. PhRMA supports HHS policies that allow individuals to identify and access the best possible health insurance options with lowest cost sharing or annual OOP costs. Plan generosity and individual patient needs also are important considerations for determining the most appropriate plans for reenrollment and PhRMA encourages HHS to incorporate these factors into the eligibility redetermination process.

Actuarial Value (AV) Threshold (§§ 156.140, 156.200, 156.400)

PhRMA supports the proposed changes, which will ensure plan metal level conforms more closely to the required AV, as envisioned by the ACA, and help reduce confusion about the differences between plans. These changes are likely to further encourage patients to enroll in silver plans with higher AV and may lead to lower overall costs for patients. This change will more fully differentiate the AV of silver and bronze plans that have different cost-sharing obligations, providing value to patients when making decisions about the plan in which to enroll.

Risk Adjustment (Part 153)

PhRMA supports HHS's decision to continue including prescription drug categories (RXCs) as an element in calculating adult risk scores. RXCs are an appropriate and important element in the model since they improve the model's predictive accuracy, especially for certain condition categories in which the predicted medical expense for a patient varies dramatically depending on whether or not a patient is receiving active treatment.

Pricing Adjustment for Hepatitis C Drugs. We recognize that as net drug prices change— and in some cases, decline—it may be appropriate to recalibrate or constrain the coefficients for particular RXCs to reflect the current market environment. While these recalibrations are

[91] Ramirez, G. et al. How ACA Marketplace Premiums Are Changing by County in 2022. December 2021. https://www.kff.org/private-insurance/issue-brief/how-aca-marketplace-premiums-are-changing-by-county-in-2022/
[92] Urban Institute. Cost and Coverage Implications of Five Options for Increasing Marketplace Subsidy Generosity. February 2021. https://www.urban.org/sites/default/files/publication/103604/cost-and-coverage-implications-of-five-options-for-increasing-marketplace-subsidy-generosity_0.pdf
[93] Karen Pollitz. Ten Changes to Watch in Open Enrollment 2022. KFF. October 29, 2021. https://www.kff.org/health-reform/issue-brief/ten-changes-to-watch-in-open-enrollment-2022/

appropriate if they are necessary to improve the model's predictive accuracy, we are concerned with HHS's assertion that without such a change, insurers would game the model by encouraging providers to prescribe particular treatments when they are unnecessary, as HHS implies with its proposal regarding the pricing adjustment for hepatitis C drugs. The professional independence and ethical standards of health care providers would prevent them from prescribing drugs that they did not believe were medically necessary and appropriate. We think the much greater concern is that the risk adjustment model could fail to adequately compensate issuers for enrollees with serious chronic conditions, and this could cause issuers to discourage enrollment by these patients, or design formularies or utilization management practices to make it difficult for patients to access innovative medicines. Thus, we encourage HHS to evaluate the model continually to ensure it fully captures the cost of the current standard of care for conditions in the model.

Risk Adjustment RXC Mapping for Recalibration. PhRMA encourages HHS to evaluate the risk adjustment model continually to ensure it fully captures the cost of the current standard of care for conditions in the model. PhRMA agrees with HHS that the inclusion of specific drugs in the risk adjustment model, or the mapping of RXCUIs to RXCs, should be reassessed in a timely manner to account for new developments, such as when new drugs that meet the criteria to be mapped to RXCs are released. As HHS defines the process for ongoing updates to RXCs, PhRMA recommends that HHS monitor trends in drug coverage on risk-adjusted plans to ensure that specific RXC mapping updates are not negatively impacting patient access to needed medications. HHS should also consider the speed of adding new drugs to the RXC mapping model after FDA approval. The timely inclusion of new drugs in the model will help ensure the incentives created by risk adjustment do not contribute to delays in the coverage of new treatments.

PhRMA appreciates the transparency provided in the rule regarding HHS' proposed approach to updates to RXC mapping. Additional visibility into the details of the process and the considerations HHS applies when determining which changes to make would be helpful to enable stakeholders to provide thoughtful comments to further improve the process. Greater transparency into the process would also allow stakeholders to plan for downstream implications of changes to RXC mapping.

Network Adequacy (§ 156.230)

PhRMA generally supports HHS's proposal to institute network adequacy standards for QHPs on the FFE, including time and distance standards. We urge HHS to institute network adequacy reviews for pharmacies, in addition to the other provider and facility types identified in the proposed rule. Network adequacy standards can indirectly impact access for certain prescription drugs, such as when a prescription drug is covered by a plan, but it needs to be dispensed or administered by specialized providers who are out-of-network, or by a specialty pharmacy. Specialized providers and specialty pharmacies are often utilized when therapies for complex, chronic conditions require special management, including additional monitoring and support services that retail pharmacies may not be able to offer. If a patient receives an otherwise covered drug from an out-of-network provider or pharmacy, which might be the only way to

receive the drug locally, the plan could consider the medicine out-of-network and might not count cost sharing toward the maximum out-of-pocket limit, creating an affordability barrier. Overly narrow pharmacy networks can have the practical impact of dissuading patients with certain complex, chronic conditions from enrolling in a plan in the first place, and thus, the adequacy of pharmacy networks should also be included in HHS's reviews.

PhRMA encourages HHS to consider such implications when implementing network adequacy standards. As discussed above, PhRMA encourages HHS to consider the need for access to culturally appropriate providers and the impact of SDOH (e.g., transportation access) when developing network adequacy standards.

Additionally, we are concerned about the accelerated growth of "pharmacy deserts," which may be exacerbated by the ongoing COVID-19 pandemic. One study showed that 630 rural communities with at least one retail pharmacy in 2003 had none in 2018.[94] Lack of pharmacy accessibility is not limited to rural areas. The lack of available pharmacies is of particular concern for the urban poor, who are less likely to use online pharmacies and more likely to let their drug regimens lapse when they can't get medication locally.[95]Additionally, a recent study on the geographic accessibility of pharmacies based on their racial/ethnic composition in the thirty most populous cities in America found persistently fewer pharmacies located in Black and Hispanic/Latino neighborhoods than white or diverse neighborhoods. In 2015, there were disproportionately more "pharmacy deserts" in Black or Hispanic/Latino neighborhoods than in white or diverse neighborhoods, and Black and Hispanic/Latino neighborhoods were more likely to experience pharmacy closures compared with other neighborhoods.[96] HHS should investigate this growing trend and consider network adequacy standards that ensure all patients have access to a local pharmacy to fill needed prescriptions.

Essential Community Providers (§ 156.235)

PhRMA supports HHS's proposal to require QHP issuers to include at least 35% of essential community providers (ECPs) in their service area in their network, up from the current 20%. Although HHS indicates that most QHP issuers already satisfy the 35% standard – and nearly all would be able to satisfy the rule through ECP write-ins or justifications – we believe the existence of a more robust standard will benefit low-income and medically underserved populations who are principally serviced by ECPs. This has the potential to make an incremental improvement in the equitable distribution of health care resources.

[94] Salako A, Ullrich F, Mueller KJ. Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018. https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf. Accessed July 21, 2021.
[95] Axios. The Growth of "Pharmacy Deserts". January 2021. https://www.axios.com/pharmacy-deserts-cities-prescriptions-45c32271-37ac-4105-b1bb-e2d2436b88c1.html
[96] Guadamuz, Jenny S., et al. "Fewer Pharmacies In Black And Hispanic/Latino Neighborhoods Compared With White Or Diverse Neighborhoods, 2007–15: Study examines pharmacy "deserts" in Black and Hispanic/Latino neighborhoods compared with white or diverse neighborhoods." Health Affairs 40.5 (2021): 802-811.

Web-Brokers (§ 155.220)

PhRMA generally supports HHS's proposals to expand the transparency that web-brokers must provide to qualified individuals, including disclosing information regarding plans that a web-broker is not appointed to sell and disclosing the basis for a web-broker's recommendations and plan prioritization. PhRMA also supports the proposal to prohibit web-brokers from accepting advertising from QHPs or prioritizing search results based on advertising by QHP issuers. PhRMA believes these changes will improve the shopping experience and will improve the likelihood that individuals select plans that are a best fit for them, taking into consideration premiums, cost sharing, benefit packages, provider networks, and drug formularies. Web-brokers are an increasingly important channel for individuals to enroll in QHP coverage and it is important that this experience results in individuals enrolling in plans that are most appropriate for their health care needs.

****

PhRMA appreciates the opportunity to provide comments regarding this proposed rule. Please feel free to contact Ashley Czin (202-835-3400) if we can provide any further information or if you have any questions about the topics discussed in our comments. We look forward to continuing to engage with the Departments on these important issues.

Sincerely,

Ashley Nathanson Czin
Deputy Vice President
Policy and Research

Lisa Lowenstein
Assistant General Counsel

Emily Donaldson
Deputy Vice President
Policy and Research