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January 27, 2022

Submitted via regulations.gov

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9911-P, P.O. Box 8016
7500 Security Blvd.
Baltimore, MD 21244-8016

Dr. Ellen Montz
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-8016

Re: RIN 0938-AU65; CMS-9911-P
Patient Protection and Affordable Care Act; HHS Notice of
Benefit and Payment Parameters for 2023

Dear Administrator Brooks-LaSure and Director Montz:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide these comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 (hereinafter NBPP 2023 Rule).

Guaranteed availability of coverage: Past due premiums (§ 147.104)

In the proposed rule, HHS revises its interpretation of the ACA's guaranteed issue provision. Contrary to the plain meaning of the statute, HHS allowed insurers to refuse to cover persons who owe past due premiums until they satisfy arrearages. We strongly support revising this incorrect interpretation of the guaranteed availability provision. The statute is clear – an issuer “must accept every employer and individual in the State that applies for such coverage.”¹ As HHS now acknowledges, denying coverage because of past-due premiums is contrary to the ACA, and disproportionately hurts persons who are low-income and others experiencing economic hardship. Especially given the ongoing and devastating impact of the COVID-19 pandemic, no one should lose or be denied health care.

We recognize the adverse selection potential for beneficiaries to only enroll in and pay premiums for care when it is needed. However, there is no evidence that consumers are attempting to “game the system.” Moreover, restrictions on mid-year enrollment outside a Special Enrollment Period (SEP) limits adverse selection. We also note that issuers have other tools to recoup unpaid premiums while still maintaining beneficiary enrollment. Issuers are required by law to accept an enrollee who makes an appropriate application for coverage during an open or special enrollment period, regardless of past due premium payments.

We strongly support revising HHS' interpretation of the ACA's guaranteed issue provision to allow individuals to enroll in coverage even if they have past-due premiums.

Nondiscrimination based on sexual orientation and gender identity - §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)

We support HHS's proposal to prohibit Exchanges, insurers, and agents and brokers from discriminating on the basis of sexual orientation and gender identity. Members of the LGBTQI+ community face discrimination, bias, and denials of care when seeking to access health care, resulting in poorer health outcomes when compared with their straight and cisgender peers. Since the Trump Administration removed the prohibitions

¹ 42 U.S.C. § 300gg-1(a).

on sexual orientation and gender identity discrimination in 2020, rates of discrimination have increased and health outcomes among the community have worsened.² HHS should proceed with reinstating these protections to improve the quality of health care received by these communities and reduce discrimination. As these purposes are consistent with the goals of the ACA, HHS has the legal authority to do so in this rulemaking.

In addition, HHS should amend the above listed sections to expressly prohibit discrimination on the basis of sex characteristics (including intersex traits). This approach would be consistent with the recent Title X family planning program final rule,³ as well as HHS's past interpretation of Section 1557 of the ACA (which it has never expressly disavowed). As with other grounds of discrimination, HHS has clear authority to adopt this prohibition to advance the purposed of the statute.

LGBTQ Discrimination and Health Disparities

The difficulty, discrimination, and disparate outcomes that members of the LGBTQ community face in health care are well-established. In the first study of its kind, fifty-six percent of lesbian, gay, and bisexual (LGB) respondents reported that they had experienced discrimination from health care providers because of their sexual orientation, including health care providers refusing to touch them or using excessive precautions, using harsh or abuse language, being physically rough or abusive, or blaming them for their health status.⁴ The same study found that seventy percent of transgender respondents reported at least one of these experiences.⁵ Other surveys found that seven percent of LGB people experienced unwanted physical contact and

² See Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities*, CTR. FOR AM. PROGRESS (Aug 18, 2021), <https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/>; Lindsay Mahowald, Sharita Gruberg, & John Halpin, Report: *The State of the LGBTQ Community in 2020*, CTR. FOR AM. PROGRESS (Oct. 2020), <https://www.americanprogress.org/article/state-lgbtq-community-2020/>.

³ HHS, Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 FR 56144, 56159, 56178 (Oct. 7, 2021), *to be codified at* 42 CFR § 59.5.

⁴ LAMBDA LEGAL, *When Health Care Isn't Caring* 5, 9-10 (2014), <https://www.lambdalegal.org/publications/when-health-care-isnt-caring>.

⁵ *Id.*



violence from a health care provider,⁶ and twenty-nine percent of transgender individuals experienced unwanted physical contact from a health care provider.⁷ Denials of care are also common. Twenty-nine percent of surveyed transgender individuals and eight percent of LGBQ individuals reported they had been refused health care because of their identity.⁸

This mistreatment results in poorer health outcomes for LGBTQ individuals than for straight and cisgender people. As HHS's Health People 2020 initiative recognized, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."⁹ Prevalent discrimination by health providers has resulted in many LGBTQ individuals delaying or avoiding needed health care or even choosing to forego care altogether because they fear being discriminated against or harmed.¹⁰ The 2015 U.S. Transgender Survey found that twenty-three percent of respondents did not see a provider for needed care because feared discrimination or maltreatment.¹¹

LGBTQ individuals already face a higher risk of both physical and behavioral health issues due to the stigma and discrimination they face in society generally.¹² Discrimination against LGBTQ individuals has been associated with higher rates of

⁶ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS, (Jan. 18, 2018), <https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/>.

⁷ *Id.*

⁸ *Id.*

⁹ *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., <https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health>.

¹⁰ See HUMAN RIGHTS WATCH, "You Don't Want Second Best": Anti-LGBT Discrimination in US Health Care 203 (2018), https://www.hrw.org/sites/default/files/report_pdf/us_lgbt0718_web.pdf; Mirza & Rooney, *supra* note 6.

¹¹ NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey 5* (2016), <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>.

¹² See HUMAN RIGHTS WATCH, *supra* note 10, at 5; Jennifer Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S.*, KAISER FAM. FOUND. (May 3, 2018), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-and-access-to-care-and-coverage-for-lesbian-gay-bisexual-and-transgender-individuals-in-the-u-s/>.



psychiatric disorders, substance abuse, and suicidality.¹³ LGBTQ individuals are also more likely to rate their health as poor, have more chronic conditions, and have a higher prevalence and earlier onset of disabilities.¹⁴ Fear of discrimination by health care providers compound with these existing disparities to result in even worse health outcomes for this community. In particular, stigma and discrimination from health care providers has been explicitly linked to increased levels of substance use among transgender individuals.¹⁵

The current rule and the Trump Administration's overall hostility towards and rollback of protections for LGBTQ individuals has exacerbated the discrimination and health disparities experienced by members of the community. A 2020 survey found that forty-seven percent of transgender respondents had experienced discrimination or mistreatment from a health provider in the prior year.¹⁶ Another survey from the same year found that thirty-six percent of LGBTQ respondents reported avoiding doctor's offices in the past year in order to avoid discrimination.¹⁷ Transgender patients and their family members have also reported increased difficulty accessing health care during the Trump Administration and after its the rollback of gender identity protections; one parent described how their "insurance company [did] not want to pay" for her son's hormone blockers "due to Trump's proposal to take away protections from the transgender community."¹⁸

While always dangerous, policies which limit or reduce LGBTQ individuals' access to affordable health coverage is particularly deadly in the context of the COVID-19 pandemic. A study from late 2020 found that one in eight, or thirteen percent, of LGBTQ people had lost health insurance since the beginning of the pandemic, more than twice the rate of non-LGBTQ people.¹⁹ In addition, twenty-eight percent of LGBTQ people

¹³ *Healthy People 2020*, *supra* note 9.

¹⁴ Kates et al., *supra* note 12.

¹⁵ Medina et al., *supra* note 2.

¹⁶ *Id.*

¹⁷ Mahowald et al., *supra* note 2.

¹⁸ Medina et al., *supra* note 2.

¹⁹ MOVEMENT ADVANCEMENT PROJ., *The Disproportionate Impacts of COVID-19 on LGBTQ Households in the U.S.* (Nov. 2020), <https://www.lgbtmap.org/file/2020-covid-lgbtq-households-report.pdf>.



reported serious problems affording medical care, again twice the rate of non-LGBTQ people (fourteen percent).²⁰

Addition of “Sex Characteristics” as a Protected Class

In addition, we recommend that HHS prohibit discrimination on the basis of sex characteristics, including intersex traits. Like other LGBTQI+ populations, intersex people face pervasive health and health care disparities, and face barriers to receiving appropriate health care and coverage.²¹ While the National Academies recently called for addressing a “significant gap” in data collection on intersex populations, substantial evidence already exists of these disparities and barriers to care.²²

Discrimination based on sex characteristics is necessarily discrimination on the basis of sex. This conclusion flows directly from *Bostock v. Clayton County*, and is supported by other precedents, including *Price Waterhouse v. Hopkins*. This interpretation has been confirmed by the federal government: prior to *Bostock*, HHS interpreted Section 1557’s sex discrimination prohibition to reach discrimination based on sex characteristics, including intersex traits, and following *Bostock*, the DOJ updated its *Title IX Legal Manual* to clarify that the *Bostock* Court’s reasoning “applies with equal force to discrimination against intersex people[.]”²³ The DOJ concluded that:

Discrimination against intersex individuals is similarly motivated by perceived differences between an individual’s specific sex characteristics and their sex category (either as identified at birth or some subsequent time). Additionally, discrimination based on

²⁰ *Id.*

²¹ See generally, Cathren Cohen, *Surgeries on Intersex Infants Are Bad Medicine*, NAT’L HEALTH L. PROG. (July 1, 2021), <https://healthlaw.org/surgeries-on-intersex-infants-are-bad-medicine/>.

²² NATIONAL ACADEMIES, *Understanding the Well-Being of LGBTQI+ Populations*, 67 (2020), <https://www.nap.edu/catalog/25877/understanding-the-well-being-of-lgbtqi-populations>; Rosenwohl-Mack A, et al., *A national study on the physical and mental health of intersex adults in the U.S.*, 15 PLOS ONE (2020); Zeeman, L., & Aranda, K., *A Systematic Review of the Health and Healthcare Inequalities for People with Intersex Variance*, 17 INT. J. ENVIRON. RES. PUB. HEALTH 6533 (2020).

²³ HHS, *Nondiscrimination in Health Programs and Activities*, 81 FR 31375, 31389 (May 18, 2016); US Department of Justice, *Title IX Legal Manual* (updated Aug. 12, 2021) (internal citations omitted), <https://www.justice.gov/crt/title-ix#Bostock>.



anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, and hormone function) is inherently sex-based. Intersex traits, like gender identity and sexual orientation, are “inextricably bound up with” sex. In other words, it is impossible to discuss intersex status without also referring to sex. Lastly, discrimination based on intersex traits may also involve sex stereotypes, as intersex people by definition have traits that do not conform to stereotypes about male or female bodies.²⁴

Recognizing that discrimination based on sexual orientation, gender identity, and sex characteristics are all inherently sex-linked, HHS rightly chose to expressly enumerate these grounds in the nondiscrimination provision of the recent Title X rule.²⁵ HHS should follow the same approach here.

Effect of Discrimination Under the NBPP

Insurers specifically have contributed to discrimination faced by the LGBTQI+ community, illustrating the need for the proposed rule. In fact, prior to the ACA, insurance companies could deny LGBT individuals, but after the law went into effect, insurance rates among LGB individual fell by almost half.²⁶ Additionally, insurers have historically employed transgender-specific exclusions to deny coverage for medically necessary treatment, including but not limited to gender-affirming treatment.²⁷ As a result, many states have chosen to enact laws to prohibit insurers from offering plans that discriminate against transgender people.²⁸

²⁴ *Id.*

²⁵ HHS, Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 FR 56144, 56159, 56178 (Oct. 7, 2021), *to be codified at* 42 CFR § 59.5.

²⁶ Lindsey Dawson et al., *The Affordable Care Act and Insurance Coverage Changes by Sexual Orientation*, KAISER FAM. FOUND. (Jan. 18, 2018), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/the-affordable-care-act-and-insurance-coverage-changes-by-sexual-orientation/>.

²⁷ Medina et al., *supra* note 2.

²⁸ See *States with health insurance bulletins prohibiting discrimination against transgender people*, TRANSGENDER L. CTR. (last updated May 23, 2016), available at <https://transgenderlawcenter.org/resources/health/bulletins>.

In addition, discrimination against intersex people in health insurance can take a number of forms, and HHS should provide one or more illustrative examples, such as the following:

- Pursuant to §§ 156.125 and 156.200(e), benefit designs that restrict coverage of EHB solely due to sex characteristics (including intersex traits) are presumptively discriminatory. For example, some health plans have adopted clinical policies for gender-affirming care that exclude such care for all adults or adolescents with intersex traits. Such a benefit design is presumed to be discriminatory if it limits coverage of an EHB when clinical evidence demonstrates that such coverage is medically necessary.
- Pursuant to §§ 156.125 and 156.200(e), benefit designs that restrict coverage of EHB due to gender coding are discriminatory to the extent that they result in restricting coverage of clinically appropriate services based on a person's gender identity, transgender status, or intersex traits. A health plan design, for example, is presumed to be discriminatory if gender coding results in denying coverage of cervical, breast, or prostate cancer screening or treatment for a transgender or intersex individual who possesses the relevant anatomy and otherwise meets criteria for coverage.

Contrary to HHS's responsibility to enhance the health and well-being of all, the prior rule's removal of sexual orientation and gender identity and exclusion of sex characteristics from nondiscrimination protections emboldened insurers who wished to withhold necessary care from LGBTQI+ individuals. By enacting the proposed nondiscrimination protections and including sex characteristics, HHS can reverse this harmful rule and, consistent with the ACA's intention, "ensure that anyone can buy insurance."²⁹

²⁹ *King v. Burwell*, 135 S. Ct. 2480, 2493 (2015).

HHS's Legal Authority Under the ACA

The proposed regulatory amendment is within HHS's authority and consistent with the Affordable Care Act's intent to improve access to health coverage and services and to prohibit discrimination in the provision of health care. In addition, as with sexual orientation and gender identity, HHS has statutory authority independent of Section 1557 to prohibit discrimination based on sex characteristics, including intersex traits, by Exchanges, insurers, and agents and brokers.³⁰

Prior to the ACA, health insurance companies routinely discriminated, including against LGBTQI+ individuals. Congress passed the ACA to put an end to these discriminatory practices. Provisions of the ACA indicated Congress's intent for the law to prohibit unreasonable barriers to obtaining appropriate medical care and remove limits on the availability of the full scope of health care a person needs.³¹

HHS has previously recognized the way that nondiscrimination provisions are inexorably linked to broader ACA requirements, stating that "a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country."³² Prohibiting discrimination by Exchanges, insurers, agents, and brokers is thus consistent with Congress' intent in enacting the ACA.

The current rule is contrary to these aims, instead permitting and creating barriers to comprehensive care. In addition, Section 1557 of the ACA clearly indicates that the law intended to prohibit discrimination in health care, and we look forward to the opportunity to provide comments on the implementing regulations of that section later this year. For all of these reasons, HHS should act to prohibit discrimination on the basis of sexual orientation, gender identity, and sex characteristics in this regulation. Without these protection LGBTQI+ individuals and their families may continue to face discriminatory barriers to appropriate and necessary medical care.

³⁰ 42 U.S.C. §§ 300gg-6(a), §300gg-92, 18022(b), 18032(e), 18041(a)(1)(B) and (D).

³¹ Pub. L. No. 111-148, sec. 18144 (Section 1554 of the ACA).

³² 81 Fed. Reg. 31379.



Federally Certified Risk Adjustment Methodology (§ 153.320)

The proposed rule would make several changes to the individual and small group market risk adjustment program. One of those proposed changes is to adopt a “two-stage” method for estimating the parameters of CMS’ risk score models. CMS indicates that the intended effect of this change is to reduce how much insurers that attract lower-risk enrollees pay into risk adjustment (which, in turn, would reduce how much insurers that attract higher-risk enrollees receive from risk adjustment).

Because higher-risk enrollees are more likely to select higher-quality plans (e.g., plans with broader provider networks, larger formularies, or less onerous utilization controls), we are concerned that this proposal would increase the premiums of higher-quality plans. This would make it harder for consumers to afford these plans and increase premium burdens for consumers with greater health care needs.

We are also concerned that this proposal would create incentives for insurers to reduce the quality of the coverage they offer, both in general and for high-risk enrollees in particular. Those types of insurer responses would exacerbate the problems that the stronger network adequacy and nondiscrimination standards that are also included in the proposed rule aim to address.

We oppose this proposal.

Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers or qualified employees enrolling in QHPs (§ 155.220)

We support the additions to this section, especially since agents, brokers and web-brokers have not been required, unlike navigators funded by marketplaces, to provide accurate and unbiased information to individuals.

Currently, web brokers in the FFM are required to display all plans available to a consumer in their rating area. Web brokers display the plans they support enrollment in – generally, those that pay commissions – but display only the insurer, plan name and type, and metal tier for those they do not sell, along with a disclaimer that more



information can be found at HealthCare.gov. The lack of additional comparative information, such as the premium and deductible, hinders consumers' ability to make meaningful comparisons between plans. The proposed rule specifies additional plan elements that must be displayed when a web broker facilitates enrollment in a plan and, for web brokers that do not, changes the disclaimer to specify that *enrollment*, not just more information, is available at HealthCare.gov. This change is a positive step but does not go far enough to allow consumers to compare plans. For example, CMS could direct web brokers to display unsupported plans in their cost comparison tools instead of segregating them at the bottom of the page. We support other important provisions that are included in the proposed rule to improve transparency for consumers. The rule would prohibit advertising or other fee-based preferential displays of plans and require web brokers to explain their rationale and methodology for recommending a plan to a consumer.

The proposed rule would also tighten the standards of conduct for agents, brokers, and web brokers to further protect consumers and give CMS additional grounds for enforcement. First, the rule prohibits discrimination based on sexual orientation and gender identity (see additional comments on the nondiscrimination provisions herein). Second, the rule spells out more specific guidelines for what it means to submit accurate client information by making it a violation to submit information such as their own business's email, phone number, or address instead of a client's information. Certain malfeasance, such as using email addresses consumers can't access or submitting inaccurate income, would also violate the rules. Third, automated interactions that lead to unauthorized enrollment or changes to enrollment would be prohibited, information used for identity proofing would need to belong to the client, and special enrollment period (SEP) eligibility would need to be ascertained individually with the consumer informed of the reason for their SEP. These things are already prohibited, yet they persist. We urge CMS to dedicate the funding necessary to support monitoring and enforcing compliance with these and all agent, broker, and web broker standards.

Annual Eligibility Determination (§ 155.335)

We appreciate HHS' request for comments on incorporating consumer costs into redetermination and reenrollment procedures. We recommend changing two policies that affect enrollees who are being renewed without making an affirmative selection of plan.

The first current policy keeps the enrollee in their past plan if it remains available during the new plan year, even if a change in market conditions has significantly raised the old plan's cost to the consumer. We recommend HHS change this policy so that when the enrollee is certain to be better off in a different plan, the enrollee is shifted to that plan, unless they opt out. The exchange would need to provide notice and reasonable opportunities, both before and after the shift, for the consumer to return to their former plan or drop coverage altogether.

This limited exception to plan continuity would apply only when:

- both plans are sponsored by the same carrier, are included in the same product, have the same provider network, and the same prescription drug formulary;
- the new plan neither has higher net premiums or lower actuarial value (AV) than the previous plan; and
- the new plan has lower net premiums, significantly higher AV, or both, compared to the former plan.

Researchers found that in Covered California's 2018 market, fully 30% of households whose coverage was automatically renewed were certain to be better off in a different plan. On average, families were charged an extra \$466 a year in annual premiums, as a result of remaining with a plan that no longer served their interests.³³

The second current policy provides that if the former plan is no longer available, the enrollee is shifted to the most similar available exchange plan offered by the same

³³ Petra W. Rasmussen & David Anderson, *When All That Glitters is Gold: Dominated Plan Choice on Covered California for the 2018 Plan Year*, MILBANK Q. (Dec. 2021), <https://www.milbank.org/quarterly/articles/when-all-that-glitters-is-gold-dominated-plan-choice-on-covered-california-for-the-2018-plan-year/>.

carrier, even if consumer costs are far higher with the new plan. This default-assignment rule assumes that the most important factor in most consumers' plan choice involves the carrier and provider networks. Such factors certainly matter to many consumers. However, with consumers who do not shop at all during the OEP, the vast majority care more about cost than carrier or provider network. Accordingly, we recommend that CMS prioritize in the default reenrollment hierarchy that when the consumer's former plan is no longer offered, keeping the consumer's net premium cost and approximate AV at levels as close as possible to (and no higher than) those in the member's plan the previous year. The notice informing the consumer of the change in plan should let the consumer opt out of the change by selecting a different plan, chosen based on the current reenrollment hierarchy, or by terminating coverage altogether. However, the default assignment, in case of complete consumer inaction, should prioritize affordability, rather than continuity of carrier and product line.

Special Enrollment Periods – Special Enrollment Period Verification (§ 155.420)

We do not support the changes to Section 155.420. For the same reasons HHS notes it is rescinding pre-enrollment verification at the FFE, it should not permit SBEs to potentially have broader pre-enrollment verification requirements. Pre-enrollment verification can hinder eligible individuals from enrolling in coverage.

As HHS notes, pre-enrollment verification can deter individuals from enrolling in coverage because of the barrier of document verification. Thus we support HHS rescinding pre-enrollment verification for all SEPs except for those losing minimum essential coverage. Yet we also recommend HHS eliminate pre-enrollment verification for that SEP too, especially knowing that many individuals often have difficulties getting documentation from prior employers about their insurance status.

If HHS does not omit pre-enrollment verification altogether, we strongly recommend that HHS only permit SBEs to utilize pre-enrollment verification for the same SEP as the FFE and not allow SBEs to potentially adopt pre-enrollment verification for other SEPs.

FFE and SBE-FP User Fee Rates for the 2023 Benefit Year (\$ 156.50)

NHeLP strongly supports a robust user fee to allow HHS to undertake a series of needed activities to adequately fulfill required Exchange functions under the Affordable Care Act (ACA). We are unsure if the proposed user fee amount will provide sufficient funding to do so, as it is difficult to assess the user fee amount without seeing the budget assumption on which it is based and the full scope of anticipated spending on activities such as navigators, improvements to healthcare.gov, and oversight.

HHS anticipates that spending on consumer outreach and education, eligibility determinations, and enrollment processes will need to increase by \$140 million above the 2022 benefit year level. This is in part due to projected enrollment declines when the enhanced premium tax credit subsidies of the American Rescue Plan Act expire and consumers will have to pay higher premiums. Despite these proposed cost increases, HHS proposes to maintain existing user fee rates in the FFEs and SBE-FPs for 2023, making it unclear how HHS will adequately fulfill these additional activities to support consumer enrollment.

HHS does not seem to be taking into consideration that additional spending to promote enrollment not only advances the purpose of the ACA - to get people living in the United States enrolled in comprehensive coverage - but it drives down costs. Modeling from Covered California, the largest state-based exchange, shows that investing in a robust marketing and outreach campaign increases Exchange enrollment, which has the direct effect of leading to a healthier risk mix and thus, lowering health care premiums by far more than any user fee savings.³⁴

By investing heavily in marketing and outreach, California's Exchange achieved a take-up rate among subsidy eligible consumers that was nearly twenty-five percent higher than the average for FFE states, and a risk score that was twenty percent lower than the national average, which drove down premiums.³⁵ Over the first five years of the Exchange's operations, this approach saved enrollees and the U.S. Treasury an

³⁴ Peter V. Lee et al., *Marketing Matters: Lessons From California to Promote Stability and Lower Costs in National and State Individual Insurance Markets* (September 2017), https://hbex.coveredca.com/data-research/library/CoveredCA_Marketing_Matters_9-17.pdf.

³⁵ *Id* at 14-15.

estimated \$12.5 billion.³⁶ HHS should consider the increased marketing and outreach efforts needed to effectively enroll consumers in the FFEs and SBE-FPs in 2023, and incorporate adequate funding in the user fee rates, even if this means an increase in the user fee rates.

NHeLP greatly appreciates HHS' substantial increase in navigator funding over the past year. We believe a strong navigator program is essential to ensuring individuals have the fair, accurate and impartial information they need to enroll and select a plan. Navigators are also uniquely positioned to help enroll low-income communities of color, limited-English proficient (LEP) individuals, immigrants, and other historically marginalized groups. NHeLP recommends even greater navigator funding, which could be supported by user fees.

Further, organizations have made numerous recommendations to improve both the consumer experience and back end systems of healthcare.gov. Some of these recommendations have been longstanding, such as making changes to application questions on HealthCare.gov to be more user-friendly and linking the appeals system to the application system. Linking the two systems would allow HealthCare.gov Call Center staff to access appeals documents, and allow appeals staff to access documents consumers have sent to healthcare.gov and to effectuate appeal decisions without having to go through CCIO. Other examples include creating a dashboard for navigators, building network adequacy standards into plan shopping options, and including funding for monitoring/enforcement. We recognize that these improvements entail significant time, resources and funding. A robust user fee should be used to address many of these issues which have lingered for years.

Further, HHS proposes new requirements on agents, brokers and web-brokers to ensure the accuracy of information they provide so as to protect consumers. HHS will need sufficient funding and resources to ensure effective oversight of these new provisions, which the user fee would support.

³⁶ Covered Cal., *Covered California's First Five Years: Improving Access, Affordability, and Accountability* 12 (December 2019), https://hbex.coveredca.com/data-research/library/CoveredCA_First_Five_Years_Dec2019.pdf.



NHeLP hopes that the proposed user fee takes into account these and other needs and provides sufficient funding to ensure significant progress and oversight. This is essential for individuals relying on the Exchanges, navigators, agents, brokers, and web-brokers. We also support making technical corrections to remove from section 156.50 all references to the Exchange Direction Enrollment (Exchange DE) option and cross-references to § 155.221(j).

State Exchange Improper Payment Measurement Program (§ 155.1500 through 155.1540)

NHeLP supports the proposal to establish a State Exchange Improper Payment Measurement (SEIPM) program that will ensure state Exchanges provide proper payments of advanced premium tax credits (APTCs), and comply with their program integrity and oversight obligations. Current regulations require that state Exchanges have safeguards in place to prevent inaccurate eligibility determinations, including APTC, CSR and enrollment errors.³⁷ However, these audits focus heavily on Exchange processes and procedures. HHS' proposal would add a new dimension of oversight by measuring the error rate of state Exchange premium tax credit payments.

NHeLP strongly recommends that the SEIPM program operate as a minimum threshold that state Exchanges must meet, and that state Exchanges that have more stringent auditing criteria should be able to maintain their existing auditing structure. This will relieve the burden on state Exchanges to hire qualified auditing entities, and allow state Exchanges to meet their programmatic audit requirements under § 155.1200(c) by completing the required SEIPM process, while also supporting more robust auditing efforts of other state Exchanges.

Error Findings Decisions (§ 155.1520)

HHS' proposal says that error findings decisions will only be provided to the respective state Exchange and will not be made public. To align with current regulations, and to preserve transparency, all state Exchange audit findings, whether done independently or through the SEIPM program, should be made public.³⁸ HHS should ensure that all

³⁷ 45 C.F.R. § 155.1200; see also 45 C.F.R. § 155.1210.

³⁸ 45 C.F.R. § 155.1200(c)(3).



state Exchange error findings decisions are posted on the HHS website so that the public can easily access these documents.

Corrective Action Plan (§ 155.1535)

NHeLP supports establishing standardized corrective action plan (CAP) obligations across all state Exchanges. We support requiring state Exchanges to develop a CAP implementation schedule and periodically evaluate whether those initiatives are effective at correcting errors identified in the audit. This will improve state Exchange operations and ultimately, improve APTC eligibility determinations for consumers. Further, all state Exchange CAPs should be made public.

Failure to Comply (§155.1540)

NHeLP supports allowing HHS to require a state Exchange to revise their corrective action plan and implementation plan if there are compliance failures. This is necessary to curtail flawed state eligibility processes, and ensure state Exchanges implement CAPs in a timely fashion.

Further, NHeLP urges HHS to gather additional information from state Exchanges that would benefit consumers. Although state Exchanges are already obligated to report some eligibility and enrollment information, we suggest gathering more robust and nuanced data on erroneous coverage denials and incorrect financial assistance allocations.³⁹ Specifically, we recommend that HHS require that state Exchanges disaggregate eligibility and enrollment data by race, ethnicity, primary language, sex, sexual orientation, gender identity, and disabilities. (See NHeLP's comments on Health Equity, Climate Health, and Qualified Health Plans for more specific data recommendations). More detailed data would identify whether or not eligibility and enrollment errors are disproportionately impacting certain groups of people, and lead state Exchanges to correct flawed eligibility processes while also tackling health equity. As one example, advocates continue to see improper denials based on immigration status. Overall, increased oversight of state Exchanges will hold state Exchanges, and

³⁹ 45 C.F.R. § 155.1200(d)(5).

their agents, accountable for incorrect eligibility determinations, and ensure that state Exchanges are operating as intended.

State Selection of EHB-Benchmark Plan for Plan Years Beginning on or after January 1, 2020 (§ 156.111)

HHS proposes to establish an evergreen deadline for states to submit revisions to their EHB benchmark selections. Instead of specifying the deadline in each NBPP, states would need to submit their new benchmark selections by the first Wednesday in May that is 2 years before the effective date of the new EHB benchmark plan. We support this proposal. Having a set date for EHB benchmark selection would help simplify the process by making submission deadlines more predictable.

We urge HHS to further strengthen and expand the transparency and public comment process for EHB benchmark selection to ensure that stakeholders and other interested parties have ample opportunity to provide meaningful input. Current rules require notice and a “reasonable” public comment period, as well as posting “associated information” on the state’s website.⁴⁰ In our own review of state benchmark decision-making, we found that most states have no established process for updating their benchmark plans. HHS should require states to adopt standards for public commenting that mirror those specified by HHS for states requesting waivers through § 1115 of the Medicaid Act.⁴¹ Those standards require states to issue a public notice that contains a “comprehensive description” of the application and “a sufficient level of detail to ensure meaningful input from the public.”⁴² In addition, states seeking a § 1115 waiver are required to give stakeholders thirty days to submit comments.⁴³ Finally, at least twenty days before submitting the § 1115 waiver application, states must hold at least two public hearings, on separate dates and at separate locations, during which “members of the public throughout the state have an opportunity to provide comments” on the demonstration

⁴⁰ 45 C.F.R. § 156.111(c).

⁴¹ For additional information about the notice and comment process for states submitting § 1115 waiver applications, see Catherine McKee & Jane Perkins, NAT’L HEALTH LAW PROG., *Section 1115 Waiver Requirements: Transparency and Opportunity for Public Comment* (2017), <https://healthlaw.org/resource/sec-1115-waiver-requests-transparency-opportunity-for-public-comment/>.

⁴² 42 C.F.R. § 431.408(a)(1)(i).

⁴³ 42 C.F.R. § 431.408(a).



application.⁴⁴ In addition, to maintain transparency and guarantee that stakeholders are able to provide meaningful input, states should include all relevant information for commenters to evaluate the proposal.

We note that only a handful of states have updated their EHB benchmark plans, even though most could add benefits and not exceed generosity limits.⁴⁵ Forty-two states, plus the District of Columbia, currently use a small group plan as the state's EHB benchmark.⁴⁶ Small group, commercial plans sold to small businesses and nonprofits are notoriously the least generous of the ten plan options available (generally, the most generous plans are the federal or state employee health benefits plans). This means that most states have considerable leeway to add benefits to address unmet health care needs and advance health equity.⁴⁷

We urge HHS to work with advocates to identify best practices in EHB benchmark selection, and provide additional guidance and training for states to update their benchmark plans.

Annual Reporting of State-Required Benefits (§ 156.111)

The proposed rule would eliminate the annual reporting of state-required benefits. We support this revision. The annual reporting requirement, imposed by the 2021 NBPP but never implemented, would purportedly help identify new benefit mandates. Under the ACA, states must defray the costs in Qualified Health Plans (QHPs) for state-mandated benefits enacted after 2011.⁴⁸ However, requiring annual reporting would overly burden both state and federal health officials. HHS already has the authority to investigate

⁴⁴ 42 C.F.R. § 431.408(a)(3).

⁴⁵ 45 C.F.R. § 156.111(b)(2)(ii).

⁴⁶ See Center for Consumer Information and Insurance Oversight, https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf (last visited Jan. 19, 2022).

⁴⁷ See Wayne Turner & Héctor Hernández-Delgado, NAT'L HEALTH LAW PROG, *The Colorado Way: Using the Essential Health Benefits benchmarking process to advance health equity* (Oct. 18, 2021), <https://healthlaw.org/the-colorado-way-using-the-essential-health-benefits-benchmarking-process-to-advance-health-equity/>.

⁴⁸ 42 U.S.C. § 18031(d)(3).



states that the agency believes are not in compliance with the defrayal of cost requirement.

There is simply no demonstrated need to require states to report all state mandates on an annual basis to show compliance. We support eliminating the annual reporting requirement for state-required benefits.

Provision of EHB (§ 156.115)

HHS proposes to eliminate the provision allowing issuers to substitute benefits between EHB categories. We strongly support this proposal, and have long been concerned that substitution between and within EHB categories could lead to adverse selection by allowing insurers to discourage enrollment by persons with significant health needs. HHS rightly recognizes the potential harm to consumers with chronic illness and disabilities if insurance companies substitute benefits between EHB categories. We also urge HHS to further ban substitution within EHB categories. In the ACA, Congress gave HHS the express authority and responsibility to define EHB, and does not allow HHS to delegate that authority to states or insurance companies.⁴⁹

Refine EHB nondiscrimination policy for health plan designs (§ 156.125)

The proposed rule clarifies insurers' obligation to comply with EHB nondiscrimination requirements and provides a regulatory framework to evaluate plan benefit design and implementation based upon clinical guidelines and evidence. We support this proposal and the examples of presumptively discriminatory benefit design. However, we have some concerns that the framework described by HHS may not fully capture discriminatory insurer practices, and urge HHS to use a broad, multi-prong approach when evaluating plan coverage and programmatic decisions.

Insurers continue to discriminate through benefit design

Before the ACA, health insurers routinely discriminated against people with pre-existing conditions, including persons with disabilities and those with chronic illness, by charging them exorbitant premiums, excluding coverage for their conditions, or refusing to

⁴⁹ 42 U.S.C. § 18022(b)(1).

provide health coverage at all. Although the ACA made these practices unlawful, some insurers still seek to discriminate through benefit design.

Insurance companies have used many features of health plan benefits and delivery to unlawfully deny needed coverage or discourage people with significant health needs from enrolling in their plans. These include exclusions, cost sharing, formularies, visit limits, provider networks, prior authorization and other utilization management that are arbitrary and not clinically based or appropriate.

However, despite these robust protections, some QHPs found new ways to discriminate against individuals with disabilities and those with serious or chronic medical conditions. For example, in 2014, NHeLP and The AIDS Institute filed a HIV/AIDS discrimination complaint with the HHS Office for Civil Rights (OCR) against four Florida issuers that placed all HIV medications, including generics, in the highest tier.⁵⁰ By placing even generic drugs on the top tier, patients faced high up-front costs in the form of expensive co-insurance and co-pays, as well as burdensome prior authorization requirements and quantity limits. These tactics are particularly hazardous for people living with HIV/AIDS. Gaps in anti-retroviral treatment can lead to the development of drug resistance and increased rates of new HIV infections.

In a study published in the New England Journal of Medicine in January 2015, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, researchers at the Harvard School of Public Health examined 48 ACA health plans and found that a dozen of these plans placed medications used to treat HIV/AIDS in the highest cost-sharing tiers.⁵¹ This practice — known as “adverse tiering” — serves to discourage people with significant health needs from enrolling in the health plan.

The Pharmaceutical Research and Manufacturers Association (PhRMA) commissioned an analysis of the formularies for 123 silver-level Marketplace plans and found similar

⁵⁰ Nat'l Health Law Program & The AIDS Inst., Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida, Administrative Complaint filed with the HHS Office for Civil Rights (May 28, 2014), <https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/>.

⁵¹ Douglas B. Jacobs, Sc.B., and Benjamin D. Sommers, M.D., Ph.D., *Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace*, N ENGL J MED 399-402 (Jan. 29, 2015).



problems regarding medications for multiple sclerosis and cancer. PhRMA concluded that there was a “lack of adequate formulary scrutiny on the part of state and federal regulators” because “[r]equiring high cost sharing for all medicines in a class is exactly the type of practice the ACA was designed to prevent.”⁵²

The National Alliance on Mental Illness (NAMI) also identified adverse tiering for medications used in the treatment of mental illness in its 2015 report: *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*.⁵³ NAMI commissioned a study of formularies for 84 health plans to assess coverage of three classes of psychiatric medications: antipsychotics, antidepressants, and SSRIs/SNRIs used commonly to treat depression. The analysis found that many plans placed these medications on high cost sharing tiers or with restricted access.⁵⁴

Adverse tiering can have serious consequences by impeding access to potentially life-saving medications. Adverse tiering works for insurers by steering persons with significant health needs, such as HIV/AIDS, away from their plans. As a result, plans with more balanced tiering structures become more likely to enroll high-need patients. Consequently, the health plan’s enrollment could become imbalanced, placing pressure on the health plan to change its coverage policies or raise premiums and/or deductibles.

HHS’ clinical guidelines standard is consistent with earlier rulemaking and guidance
HHS takes the right approach, establishing that nondiscriminatory benefit design is clinically based and incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. The clinical guidelines standard that HHS proposes is consistent with earlier HHS rulemaking and guidance. However, we ask that HHS consider our concerns regarding bias in peer-reviewed journals and data, and the connection of those issues to clinical guidelines discussed below to make changes that will protect against the use of improper use of clinical guidelines as a shield.

⁵² PhRMA, Coverage Without Access: An Analysis of Exchange Plan Benefits for Certain Medicines, <http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines#sthash.o0bB3Xh0.pdf>.

⁵³ NAMI, *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care* (April 2015) at 7; available at <https://www.nami.org/About-NAMI/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-ALongRoadAhead.pdf>.

⁵⁴ *Id.*



HHS has previously described its review of prescription drug coverage for compliance with EHB nondiscrimination requirements, identifying

four medical conditions: bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. The purpose of the analysis is to ensure that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions, and on some first line drugs, are not restricting access through lack of coverage and inappropriate use of utilization management techniques.⁵⁵

In another example, HHS concluded that plans that cover some treatments for HIV, but fail to cover the standard of care for HIV treatment, single tablet therapy, are discriminatory.⁵⁶

HHS clinical guidelines framework proposed here should be part of a multi-prong approach to evaluating plans for discriminatory design and delivery. HHS should continue to employ other tools, such as outlier analyses, which it recognized can reveal problematic plan design, such as if a plan is improperly subjecting a large number of drugs within a particular category or class to prior authorization and/or step therapy.⁵⁷ HHS asked for comment on the 60-day applicability date for nondiscrimination standards. We fully support this timeframe. Since the proposed clinical standards framework is consistent with HHS earlier rulemaking and plan compliance reviews, it should not unduly burden issuers to review and update their plans for compliance.

HHS' proposed framework raises additional questions and concerns

We appreciate the proposed addition in § 156.125(a) and the framework as described in the preamble. While this represents a promising starting point for evaluating plans, it

⁵⁵ Ctrs. for Medicare & Medicaid Servs, Ctr. for Consumer Info. & Ins. Oversight, Final 2016 Letter to Issuers in the Federally-Facilitated Marketplace (Feb. 20, 2015) at 41, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/184740_2016_Letter_to_Issuers_2_20_2015_R.pdf. See also HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750, 10,822- 10,823 (Feb. 27, 2015), <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

⁵⁶ *Id.*

⁵⁷ 2016 NBPP Rule, 80 Fed. Reg. 10,822.



may not capture the full range of discriminatory practices and could unintentionally reinforce bias. For example, clinical guidelines may be silent on the practice of requiring people to access prescription drugs through mail order, but such practices would be discriminatory against persons who are transient or face stigma due to their medical conditions, such as people living with HIV and AIDS.⁵⁸ HHS previously recognized that this practice may be discriminatory and prohibited EHB plans from requiring mail order-only pharmacy benefits.⁵⁹ As HHS explained, “[M]aking drugs available only by mail order would discourage enrollment by, and thus discriminate against, transient individuals and certain individuals who have conditions that they wish to keep confidential.”⁶⁰ Relying exclusively on clinical guidelines and journal articles could unduly limit HHS’ plan analysis for discriminatory design. Moreover, an insurer could cite a single peer-reviewed article to justify a discriminatory plan feature.⁶¹ We agree that plan design should clinically-based and incorporate “evidence-based guidelines into coverage and programmatic decisions.” However, the reliance on current and relevant peer-reviewed medical journal articles could prove problematic. For example, as noted with the mail order pharmacy example, an issuer could point to a single peer-reviewed study to justify coverage limits or exclusions and avoid providing the standard of care in the treatment of certain conditions. We also note that peer-reviewed journals can perpetuate health disparities. Recent research has identified that peer-reviewed medical journals can have a significant racial bias.⁶² This compounds

⁵⁸ See Wayne Turner & Shyaam Subramanian, NAT’L HEALTH LAW PROGRAM, *EHB Prescription Drug Standard Issue No. 3 – Mail-Order Pharmacies* (June 22, 2015), <https://healthlaw.org/resource/ehb-prescription-drug-standard-issue-no-3-mail-order-pharmacies/>.

⁵⁹ 45 C.F.R. § 156.122E.

⁶⁰ 2016 NBPP Rule, 80 Fed. Reg. at 10,821. see also HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12,204, 12,312-13 (Mar. 8, 2016), <https://www.govinfo.gov/content/pkg/FR-2016-03-08/pdf/2016-04439.pdf> (declining request to retract EHB prohibition on mail order only pharmacy requirements).

⁶¹ See, e.g., Julie A Schmittiel et al., *The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients*, Am. J. Managed Care (Nov. 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278640/> (showing that that mail order pharmacy can help some patients with medication adherence).

⁶² Rhea Boyd et al., *The World’s Leading Medical Journals Don’t Write About Racism. That’s a Problem*, TIME (Apr. 21, 2021) (finding that the top four medical journals in the world almost never publish scientific articles that name racism as a driver of poor health outcomes and less than 1% of the 200,000 articles published over the past 30 years included “racism” anywhere in the text; of the few articles that did, 90% were predominately opinion pieces); Usha Lee

acknowledged bias in clinical trials, data sets, and how clinician bias may affect data.⁶³ And since most health care guidelines are based on this information, bias often gets compounded again, not to mention the impact of financial considerations that often come into play in coverage guidelines.⁶⁴

Health care has a long history of institutional bias that includes explicit and implicit bias, and has centered the white, heteronormative experience.⁶⁵ Data collection, research, determinations regarding cause and outcomes, and analyses can be informed by institutional bias within the system.⁶⁶ This does not mean that peer-reviewed journals,

McFarling, *When a Cardiologist Flagged the Lack of Diversity at Premier Medical Journals, the Silence was Telling*, STAT (Apr. 12, 2021), <https://www.statnews.com/2021/04/12/lack-of-diversity-at-premier-medical-journals-jama-nejm/> (discussing the impact on research from the lack of diversity at premier medical journals).

⁶³ E.g., Donna Christensen et al., *Medical Algorithms Are Failing Communities of Color*, HEALTH AFFS. FOREFRONT (Sept. 9, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210903.976632/full/> (citing the lack of diversity in medical data, including clinical trials and the failure of data based tools to reflect the population they are being used on); Michael Sun et al., *Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record*, HEALTH AFFS. (Jan. 19, 2022), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01423> (finding Black patients had 2.54 times the odds of having at least one negative descriptor in their EHR); Ziad Obermeyer, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447 (Oct. 25, 2019), <https://science.sciencemag.org/content/366/6464/447> (identifying racial bias in health care allocation algorithm because it was based in spending rather than need); see generally Melissa D. McCradden et al., *Ethical Limitations of Algorithmic Fairness in Health Care Machine Learning*, 2 THE LANCET E222 (May 2020); Ibram x. Kendi, *There is No Such Thing as Race in Health-care Algorithms*, 1:8 THE LANCET E375 (Dec. 2019), [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(19\)30201-8/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30201-8/fulltext); Rachel R. Hardeman, Eduardo M. Medina & Katy Kozhimannil, *Structural Racism and Supporting Black Lives—The Role of Health Professionals*, 375 NEW ENG. J. MED. 2113 (Dec. 1, 2016) (summarizing sources of bias in health care).

⁶⁴ See, e.g., *Wit v. United Behavioral Healthcare*, 14-cv-2346-JCS, 2019 WL 1033730 (N.D. Cal. July, 27, 2020) (finding parity compliance issues with utilization management tools that used criteria that did not align with clinically accepted criteria and was unduly influenced by fiscal rationales).

⁶⁵ See, e.g., Kendi, *supra* note 63; Hardeman, *supra* note 63; Michael Sun et al., *Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record*, 41 HEALTH AFFS. 1 (Feb. 2022), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01423>.

⁶⁶ See, e.g., Hannah E Knight et al., *Challenging Racism in the Use of Health Data*, 3:3 THE LANCET E144 (Feb. 3, 2021) (explaining how structural inequalities, biases, and racism in

clinical guidelines, and the like should not be relied upon for determining medical necessity or the appropriateness of care, but we are concerned that relying on them exclusively opens the door for plans to use this type of research as a shield and escape valid claims of discriminatory benefit design.⁶⁷ HHS' proposed framework could create a battle of experts which could obviate insurer culpability for discriminator plan design. In addition, there is often a lack of transparency about the data and underlying assumptions of studies and tools that makes it difficult to call into question their validity, especially when many are protected as trade secrets or intellectual property. Because of these acknowledged biases, HHS should use a multi-prong approach in evaluating plans health plan coverage and programmatic decisions, protect against the creation of safe harbors for benefit design, and improve transparency. HHS should consider other types of research to help inform coverage and programmatic decisions. Community-based research is a crucial way of identifying unmet health needs and accurately of assessing the needs and preferences of people experiencing barriers to care. For example, a recent report from the Healthy California for All Commission shows that communities, particularly those representing Black, Indigenous, and other people of color, want to have input in the design of health care systems and seek research that highlights their experiences.⁶⁸

A critical component of identifying discriminatory benefit design and whether there is discriminatory design behind what may appear to be facially neutral policies is

society are easily encoded in datasets and application of data science and how it can reinforce existing injustices and inequalities).

⁶⁷ When HUD proposed language that would have allowed a degree of deference to algorithmic decision making in disparate act claims, there was significant push back because of the institutional racism in housing, the prevalence of proxy discrimination, and other issues with relying on an algorithm in that field. Health care has similar deeply engrained institutional biases. See, e.g., Elizabeth Edwards, David Machledt & Hannah Eichner, NAT'L HEALTH LAW PROGRAM, *Comments on HUD Disparate Impact Rule Changes and the Use of Algorithms* (Oct. 18, 2019), <https://healthlaw.org/resource/comments-on-hud-disparate-impact-rule-changes-and-the-use-of-algorithms/>; Deborah Archer, AI Now Institute and Ctr. on Race, Inequality & the Law, *Comments on HUD's Implementation of the Fair Housing Act's Disparate Impact Standard* (Oct. 18, 2019), <https://www.regulations.gov/comment/HUD-2019-0067-2746>.

⁶⁸ Healthy California for All Commission, *Community Voices: Priorities and Preferences of Californians with Low Incomes for Health Care Reform* (Oct. 2021), <https://www.chhs.ca.gov/wp-content/uploads/2021/10/Final-Report-Community-Voices-Priorities-and-Preferences-of-Californians-with-Low-Incomes-for-Health-Care-Reform-October-2021.pdf>.



transparency. HHS should consider approaches to compliance borrowed from mental health parity enforcement, particularly disclosure requirements. A key component of identifying discriminatory design is transparency, not only of the written policy, but of the underlying data, justification, and other decision steps.⁶⁹ Although disclosure under mental health parity has not yet reached its promise, the impact of greater transparency has shown itself in the cases enforcing parity.⁷⁰ In addition, transparency is critical to revealing sources of bias, not only in design but in data sources, algorithms, research, and the like.⁷¹

We are also concerned that the proposed framework could inadvertently inhibit efforts to advance health equity and end disparities. For example, the DC Health Benefit Exchange Authority (DCHBX) agreed to modify standardized plans to eliminate cost-sharing, including deductibles, co-insurance, and co-payment, for medical care, prescription drugs, supplies and related services that prevent and manage diseases and health conditions that disproportionately affect people of color in the District of Columbia.⁷² This laudable effort, and others like it, could conceivably run afoul of HHS' nondiscrimination framework by differentiating cost sharing for certain conditions, like

⁶⁹ See Elizabeth Edwards et al., NAT'L HEALTH LAW PROGRAM, NHeLP AHRQ Comments (June 10, 2021), <https://healthlaw.org/resource/nhelp-ahrq-comments/> (regarding the need for transparency in assessment tools, guidelines, and other health care tools); NHeLP et al. Amicus Brief in *N.R. v. Raytheon*, <https://healthlaw.org/resource/amicus-n-r-v-raytheon-company-u-s-court-of-appeals-first-circuit/> (discussing the important function of mental health parity disclosure requirements and the challenges with enforcing that requirement).

⁷⁰ See, e.g., *Wit v. United Behavioral Healthcare*, 14-cv-2346-JCS, 2019 WL 1033730 (N.D. Cal. July, 27, 2020) (finding parity compliance issues with utilization management tools that used criteria that did not align with clinically accepted criteria and was unduly influenced by fiscal rationales); see also NHeLP et al. Amicus Brief in *Wit v. United Health Care*, <https://healthlaw.org/nhelp-files-friend-of-court-brief-to-protect-access-to-promised-behavioral-health-care/>.

⁷¹ Obermeyer et al., *supra* note 63; NHeLP AHRQ Comments, *supra* note 69, at 12-30 (discussing issues of bias in health care algorithms and the need for greater transparency).

⁷² DC Health Benefit Exchange Authority (DCHBX), Press Release, *DC Health Benefit Exchange Authority Takes Action to Achieve Social Justice and Equity in Health Insurance Coverage* (July 15, 2021), <https://dchealthlink.com/node/3569>. See also DC Health Benefit Exchange Authority Social Justice & Health Disparities Working Group, *Recommendations of the Social Justice & Health Disparities Working Group to the District of Columbia Health Benefit Exchange Authority* (July 12, 2021), https://hbx.dc.gov/sites/default/files/dc/sites/hbx/event_content/attachments/HBX%20Social%20Justice%20and%20Health%20Disparities%20Working%20Group%20Final%20Report.pdf.

Type 2 diabetes and HIV, that disproportionately affect communities of color. HHS should clarify that activities to reduce health disparities would not violate EHB nondiscrimination requirements.

HHS should clarify that nondiscrimination compliance does not trigger defrayal

While NHeLP supports HHS' efforts to better enforce nondiscrimination requirements, the proposals and examples omit an important component in the fight against discriminatory benefit designs: state mandates in addition to EHBs. We believe the preamble to the proposed rule is clear about nondiscrimination requirements extending to state mandated benefits that are part of the EHB package (that is, state mandates passed through state action before January 1, 2012 or benefits added to the EHB package through the benchmarking process, which HHS has clarified are not subject to defrayal regardless of the benchmarking option pursued by the state). However, to our dismay, the preamble is silent about situations in which states enact new state mandates through state action for the purpose of ensuring compliance with federal nondiscrimination requirements. NHeLP strongly believes such a mandate should be considered part of the EHB package and as such, not subject to defrayal requirements, and we urge HHS to provide explicit guidance and clarity for states contemplating these mandates.

For example, recent federal court decisions have found that categorically excluding certain durable medical equipment (DME) (such as hearing aids) from coverage likely runs counter to federal nondiscrimination requirements, including Section 1557. States are also grappling with ensuring equity in family planning services, including coverage for vasectomies and external condoms.⁷³ As a result, states may now wish to enact mandates clarifying that the EHB category of rehabilitative and habilitative services must include coverage for these devices in order to avoid discriminatory benefit designs. We believe this action should classify as an exemption to the state mandate defrayal requirement pursuant to 45 C.F.R. § 155.170(a)(2) because the mandate is enacted for the purpose of complying with federal law and, as such, should be considered part of the EHB package. HHS should use the opportunity afforded by the NBPP 2023 to provide assurance to states that these types of mandates will not be

⁷³ See Liz McCaman Taylor, NAT'L HEALTH LAW PROGRAM, *Contraceptive Equity & Essential Health Benefits* (Dec. 2021), <https://healthlaw.org/resource/contraceptive-equity-primers/>.

subject to defrayal and, in so doing, provide an additional avenue for states to enforce federal requirements of nondiscrimination in plan design.

We also believe HHS could take a step further to protect Marketplace enrollees from discriminatory benefit design by exempting from defrayal state mandates enacted pursuant to state nondiscrimination requirements. We recognize that some states may have nondiscrimination standards that are more stringent than federal requirements and we believe states should have considerable leeway to enforce those without being subject to defrayal requirements. We thus urge HHS to amend 45 C.F.R. § 155.170 to reflect that benefits added through state mandate for the purpose of complying with either federal *or state* requirements would be considered part of the EHB package and not subject to defrayal.

We welcome HHS' proposal to address discriminatory plan benefit design and delivery and look forward to providing further assistance in ending these harmful insurer practices.

Cost-sharing requirements (§ 156.130)

Co-Pay Accumulators

Many healthcare consumers struggle to afford prescription drugs due to high cost-sharing in the form of co-pays or co-insurance; and high deductible plans where consumers must pay out-of-pocket for services, including prescription drugs, until insurance will cover health care costs. For this reason, many consumers rely on pharmaceutical manufacturers' coupons to help defray cost sharing of prescription medications. However, under the NBPP 2022 advanced by the previous administration, issuers are allowed to not count coupons towards a consumer's deductible and out-of-pocket maximum, even when there is no generic alternative.⁷⁴ As a result, when coupons run out, the consumer pays the full amount for a drug until meeting the deductible; and continue to pay cost-sharing until reaching the out-of-pocket maximum. Despite the urging of numerous patient groups, the proposed NBPP 2023 fails to include language that reverts to the 2020 NBPP rule requiring insurers to count copay

⁷⁴ 85 Fed. Reg. 7158, *codified as* 45 C.F.R. § 156.130(h).

assistance towards a patient's annual deductible or out-of-pocket maximum, with limited exceptions. Patients rely on copay assistance to afford the drugs prescribed by their provider. For many patients with complex illnesses, there are no generics or low-cost alternative options available.

Under the current rule, many patients will no longer be able to access potentially life-saving medication because they cannot afford it. The consequences are entirely predictable – with fewer prescriptions filled and disruptions in treatment and worse health outcomes.⁷⁵ Gaps in treatment can have deadly consequences for some,

⁷⁵ See e.g., Joel F. Farley, *Medicaid Prescription Cost Containment and Schizophrenia*, 48 MED. CARE 440–447 (2010) (finding that aggressive cost-containment policies in Mississippi caused patients to be 4.87% less compliant with antipsychotic treatments, in addition to experiencing 20.5% more 90-day antipsychotic treatment gaps); Teresa B. Gibson et al., *The Effects of Prescript Drug Cost Sharing: A Review of the Evidence*, 11 AM. J. MANAGED CARE 730–40 (2015) (finding that higher levels of prescription drug cost sharing can cause treatment disruptions such as lower levels of treatment adherence, initiation, and continuation, especially for chronically ill patients); Daniel M. Hartung et al., *Impact of a Medicaid Copayment Policy on Prescription Drug and Health Services Utilization in a Fee-for-Service Medicaid Population*, 46 MED. CARE 565–572 (2008) (finding that copay implementation significantly decreased utilization of prescription drugs, especially for patients with diabetes, respiratory diseases, and schizophrenia); Nantana Kaisaeng et al., Carroll, *Out-of-Pocket Costs and Oral Cancer Medication Discontinuation in the Elderly*, 20 J. MANAGED CARE PHARMACY 669–675 (2014) (finding that high out of pocket costs cause patients to delay or discontinue their drug therapy); Deliana Kostova & Jared Fox, *Chronic Health Outcomes and Prescription Drug Copayments in Medicaid*, 55 MED. CARE 520–527 (2017) (estimating that the drug copayments in Medicaid are associated with an average rise in uncontrolled hypertension and uncontrolled hypercholesterolemia); Sujha Subramanian, *Impact of Medicaid Copayments on Patients With Cancer*, 49 MED. CARE 842–847 (2011) (finding that use of copayments does not decrease overall cost, and can lead to negative consequences such as decreasing the number of days of supply of prescription drugs, reducing use of prescription drugs for patients with multiple comorbidities, increasing emergency room visit, and so on); see also Samantha Artiga et al., *The Effects of Premium and Cost-Sharing on Low-Income Populations: Updated Review of Research Findings*, KFF (Jun. 01, 2017), <https://www.kff.org/report-section/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings-table-2/> (highlighting several national and state level studies on the effects on cost-sharing). Ridley D.B., Axelsen K.J., *Impact of Medicaid preferred drug lists on therapeutic adherence*. 24 *PharmacoEconomics* 65 (2006) <http://www.ncbi.nlm.nih.gov/pubmed/17266389>. See also Happe LE, Clark D, Holliday E, Young T, *A systematic literature review assessing the direction impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resources utilization*, J MANAG CARE SPEC PHARM; 207):67-84 (2014); Mullins CD, Shaya FT, Meng F, et al., *Persistence, switching, and*

including people living with HIV/AIDS where “even short interruptions of care can threaten health and undermine prevention effects.”⁷⁶

We strongly urge HHS to prohibit the use of copay accumulator adjustment policies, which discriminate against people living with chronic illness and disabilities who rely on prescription drug coverage.

Standardized Plan Options (§ 156.201)

NHeLP strongly supports HHS’ proposal to require issuers in the federally facilitated exchanges and state-based exchanges that use the federal platform to offer at least one standardized plan at every product network type, metal level, and in every service area where the issuer also offers non-standardized plans. In first place, we commend HHS for proposing to correct the changes implemented in the NBPP 2019, under which the previous administration eliminated a provision encouraging issuers to offer standardized plans and requiring designation and preferential display on HealthCare.gov. However, simply undoing the previous rule is not enough to address consumer confusion and choice overload in the Marketplace. As such, we are encouraged to see that HHS is requiring plan standardization as an important step in the right direction towards improving consumer experience.

A recent Assistant Secretary for Planning and Evaluation (ASPE) issue brief indicates that “almost three quarters of *HealthCare.gov* consumers have *more than 60 plan options* to choose from, and the average number of plans is *over 100*” (emphasis added).⁷⁷ Because health care is not a typical consumer good, the usual understanding that more is better for the consumer does not hold true in the Marketplace. On the

discontinuation rates among patients receiving sertraline, paroxetine, and citalopram, Pharmacotherapy 25-660-7 (2005).

⁷⁶ See *Drug Resistance*, AIDS INFO (Jan. 28, 2019), <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance>; Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 HEALTH AFFAIRS, 430 (2014).

⁷⁷ HHS, Assistant Sec’y for Plan. and Evaluation (“ASPE”), *Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces 1* (2021), <https://aspe.hhs.gov/sites/default/files/documents/222751d8ae7f56738f2f4128d819846b/Standardized-Plans-in-Health-Insurance-Marketplaces.pdf>.



contrary, the high number of plan options often leads to confusion among shoppers, which in turn gives way to consumer errors during plan selection. As the ASPE reports finds, a higher number of plan options runs counter to the central premise of the Affordable Care Act (ACA), which relies on plan competition to increase the value of health care and requires informed consumers to continuously “select among competing plans to realize that value.”⁷⁸ Choice overload, on the other hand, often leads consumers to make selections without regards to value and disincentivizes consumers from switching from lower-value plans to higher-value plans.

While HHS’ proposal does not directly limit the number of plan options available to consumers in the Marketplace, requiring all issuers to offer at least one standardized plan in each tier and service area where they offer non-standardized plans will nonetheless enable consumers to make apples-to-apples comparisons of plans sharing a common benefit and cost-sharing structure. The ACA generally achieved common benefit structure across plans through the requirement that Marketplace plans cover essential health benefits (EHBs), but lack of cost-sharing standardization has allowed issuers to offer an unlimited number of plans across the different exchanges. Through the new standardization proposal, consumers would be able to compare plans without regards to cost-sharing requirements, allowing individuals to focus on other factors that are better indicators of the plan’s value and that are more crucial to consumers’ health, such as premiums, provider network, and quality of services.

Standardization also serves as a tool to improve affordability and address health disparities in the Marketplace. HHS’ proposal will ensure that consumers always have access to at least one plan that exempts certain essential services, including emergency room services, primary care visits, and mental health and substance use disorder treatment, from deductibles. Because people of color and other underserved populations often lack access to such services that are key to prevent further health complications, exempting these services from the deductible in all standardized plans will make it easier for these communities to receive the care they need and help close gaps in access to care.⁷⁹

⁷⁸ *Id.* at 4.

⁷⁹ For a discussion about how issuers use benefit manipulation and “adverse tiering” to discriminate against individuals with high-cost needs and how standardization helps fix this problem, see Douglas Jacobs, *CMS’ Standardized Plan Option Could Reduce Discrimination*, HEALTH AFF. (2016), <https://www.healthaffairs.org/doi/10.1377/forefront.20160106.052546>.

NHeLP also support the standardization proposal because it will ensure consumers have access to more services subject to copayments instead of coinsurance. Preference of copayments over coinsurance is particularly important for certain services, such as prescription drugs, for which actual prices vary considerably, given that consumers are ill-equipped to consider these price variations. By making prescription drug prices more uniform, emphasizing copayments over coinsurance improves affordability for individuals who need access to specialty (and costlier) drugs to treat their conditions, including HIV, cancer, rheumatoid arthritis, and other chronic conditions. Coinsurance also increases confusion among consumers because even more experienced consumers may fail to understand that a lower coinsurance percentage may nonetheless represent a higher out-of-pocket amount than copayments. As such, preference of copayments over coinsurance will enable consumers to select higher-value plans that utilize copayments over lower-value plans with coinsurance.

The effectiveness of standardization in improving access and affordability is evident by the experience of the nine states and the District of Columbia that have already adopted standardization in their state-run exchanges. In particular, our experience as consumer advocates in California, the only state that requires *all* plans in the Marketplace to be standardized, solidifies our support for HHS' standardization proposal. California has required all plans to be standardized since Covered California's inception in 2014. The result of this policy has been that consumers are able to navigate the Marketplace and shop around without having to worry about price variation within particular tiers and service areas. In turn, this ease of access has led to robust coverage across all counties in California alongside significant, albeit incomplete, improvements in the quality of care provided due to competition being based on plans' overall value instead of cost. Despite our strong support for the standardization proposal, we are concerned that some of the cost-sharing HHS has proposed as part of standardized plans remains too high and unaffordable for beneficiaries with high needs. For instance, while we commend HHS for proposing to exempt some prescription drugs from deductibles across most plan tiers, this is not the case for most specialty drugs. These medications are typically prescribed for treatment of challenging conditions and access to them is essential for the well-being of individuals living with chronic conditions and high-cost needs. To improve affordability of these drugs, we recommend that HHS exempts them

from deductible requirements across silver plans, which represent the bulk of enrollment in the Marketplace. In addition, copays for specialty drugs remain too high and unaffordable for most individuals under the proposal. As such, we urge HHS to evaluate the possibility of lowering copayments for specialty drugs without the need to increase cost-sharing for other services pursuant to the AV calculator.

Network Adequacy (§ 156.230)

We commend HHS for revisiting these regulations to add new provisions aimed at ensuring that QHP enrollees have meaningful access to all essential health benefits. Our experience over the last decade has demonstrated that measurable network adequacy standards that are regularly monitored and enforced are crucial to ensuring people's access to care.⁸⁰ Robust network adequacy standards are a crucial step to ensuring that people have access to the services they need. Moreover, experience from both federal and state programs has demonstrated that a layered approach to network adequacy – one that accounts for both potential and realized measures of access, and that employs multiple strategies to monitor and enforce compliance with network standards – is the most effective way to ensure that people can actually get the right care in the right place at the right time.⁸¹ Moreover, all stakeholders benefit when the standards are clear and easy to measure. Without measurable standards, neither issuers nor other stakeholders will understand how QHP networks are being evaluated, and when CMS will consider them to be reasonable. Without specific standards, consumers and advocates also will not know whether access problems they experience warrant a complaint to HHS. We appreciate that HHS is taking several important steps

⁸⁰ See, e.g., Jane B. Wishner & Jeremy Marks, Urban Inst., *Ensuring Compliance with Network Adequacy Standards: Lessons from Four States* 3 (2017), https://www.urban.org/sites/default/files/publication/88946/2001184-ensuring-compliance-with-network-adequacy-standards-lessons-from-four-states_0.pdf; Ellen Weber, Legal Action Ctr., *Spotlight on Network Adequacy for Substance Use Disorder and Mental Health Services* (2020), <https://www.lac.org/resource/spotlight-on-network-adequacy-standards-for-substance-use-disorder-and-mental-health-services>.

⁸¹ See, e.g., Mark A. Hall & Paul B. Ginsburg, USC-Brookings Schaeffer Initiative for Health Policy, *A Better Approach to Regulating Provider Network Adequacy* (2017), <https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf>.

in this proposed rule to implement such a layered approach to ensure that QHP enrollees can get the services they need.

We support HHS's proposal to evaluate networks of QHPs and potential QHPs in the FFE prior to their certification, and post-certification review of compliance with appointment wait time standards in response to random sampling or complaints. We urge HHS to closely scrutinize both the standards and review process before allowing states that perform plan management functions to perform their own reviews of network adequacy to ensure that both are indeed at least as stringent as the established federal standards, and that networks are reviewed before QHPs are certified. We emphasize that network adequacy reviews, whether performed by HHS or by states, must include direct testing, such as secret shopper surveys, or data systems that capture appointment details.

Cost-sharing in tiered networks (§ 156.230(a)(1))

We strongly support HHS's proposal to require QHPs with tiered networks to meet the network adequacy standards in the lowest cost-sharing tier. To truly demonstrate that QHP networks are adequate, QHP issuers must be able to ensure that enrollees always have the option to use an in-network or first tier provider for all covered services. At the same time, as discussed in more detail below, we urge HHS to also clarify that in any situation where a QHP network does not comply with network adequacy standards in its first tier, the QHP may not charge the enrollee more than the first tier cost-sharing for seeing an out-of-network or higher tier provider. This protection is necessary to ensure that the promise of first tier network adequacy is real.

Network Adequacy Standards for SBEs § 156.230(a)(2)(i)

NHeLP encourages HHS to set a national floor for network adequacy in all Exchanges. HHS should ensure that QHPs in SBEs are subject to at least the same standards that are applied to their counterparts in the FFE. To balance the need for a national standard and state flexibility, we encourage HHS to allow states to perform their own reviews of network adequacy as long as both the standards and review process are at least as stringent as the established federal standards and process. Over the last decade, many states have acted to require plans in their states to meet quantitative network adequacy



standards, including both time and distance and appointment wait time standards in several jurisdictions.⁸² Some states have adopted provisions that apply broadly to private carriers in their state, including those participating in an SBE, while in other cases, SBEs have adopted their own standards for participating providers, and in some states, both broader state network adequacy standards and SBE-specific provisions apply.⁸³ The result is a confusing patchwork for QHP enrollees, which has too often resulted in lack of access.

While we support HHS's leaving the states and OPM with ample room to hold QHPs to higher standards, reflecting the particular needs of each state, we urge HHS to establish a national floor for network adequacy in these regulations. The current approach to network adequacy standards has resulted in consumer protections varying widely across state lines. HHS should address this by adopting a federal minimum standard that will apply to all QHP issuers in all Exchanges. We again emphasize that network adequacy reviews, whether performed by HHS or by states, must include direct testing, such as secret shopper surveys, or data systems that capture appointment details.

RECOMMENDATION: We suggest that HHS amend § 156.230(a)(2)(i) as follows:

(2)(i) Standards. For plan years beginning on or after January 1, 2023, a QHP issuer ~~on a federally facilitated Exchange~~ must **at a minimum** comply with the requirement in paragraph (a)(1)(ii) of this section by:

Time and Distance Standards (156.230(a)(2)(i)(A))

We strongly support HHS's proposal to codify provider and facility types that will be subject to time and distance standards, and particularly support listing the provider and facility types subject to these standards in the text of the regulation. Time and distance

⁸² See, e.g., Nat'l Conf. State Leg., *Insurance Carriers and Access to Healthcare Providers: Network Adequacy* (2018), <https://www.ncsl.org/research/health/insurance-carriers-and-access-to-healthcare-providers-network-adequacy.aspx>; Ellen Weber, Legal Action Ctr., *Spotlight on Network Adequacy Standards for Substance Use Disorder and Mental Health Services* (2020), <https://www.lac.org/resource/spotlight-on-network-adequacy-standards-for-substance-use-disorder-and-mental-health-services>.

⁸³ See Wishner et al., *supra* note 80.

standards are a key measure of enrollees' potential access to care. After all, if a QHP's provider network only includes providers who are hundreds of miles away from its enrollees, it has not provided sufficient access to covered services.⁸⁴ Ensuring that care is available within a reasonable distance from where enrollees are is crucial.

We support the categories identified by HHS, and suggest that HHS consider expanding them to ensure that they account for the full range of provider and facility types necessary to deliver covered essential health benefits.

We are particularly supportive of the quantitative values required for travel time/distance for Outpatient Clinical Behavioral Health professionals. Conforming those values to the time/distance values for Primary Care (adult and pediatric) providers appropriately reflects that many patients with mental health and substance use conditions rely on their behavioral health provider as their "primary care" practitioner and enter the health care system through those providers. The relatively short travel time and distance values also recognize the dire need for readily accessible outpatient therapeutic services and should incentivize QHPs to expand provider networks for these services.

We also commend HHS for making clear that "Outpatient Clinical Behavioral Health" providers can include licensed, accredited, and certified professionals. We urge HHS to consider adding more granularity with respect to the categories of behavioral health providers that must be measured, to include providers of Medication Assisted Treatment (MAT), methadone clinics, detoxification services, substance use crisis services, and mental health crisis services. In addition, we recommend that HHS separately evaluate time and distance for pediatric providers from adult providers. MAT in particular is considered the "gold standard" for substance use disorder treatment, and should be separately measured to ensure QHP enrollees can access it.⁸⁵ At a minimum, we suggest that HHS split this category into two groups, one for "Outpatient Clinical Mental Health" providers and another for "Outpatient Clinical Substance Use Disorder"

⁸⁴ See, e.g., Stephen C. Dorner et al., *Adequacy of Outpatient Specialty Care Access in Marketplace Plans Under the Affordable Care Act*, 314 J. AM. MED. ASSN. 1749 (2015), <http://jama.jamanetwork.com/article.aspx?articleid=2466113>.

⁸⁵ U.S. Dep't Health & Hum. Servs., Off. Surgeon Gen., *Facing Addiction in America: The Surgeon General's Spotlight on Opioids 2* (2018), https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf.

providers. Putting all behavioral health providers into one category could cover up shortages of either mental health or substance use disorder service providers, and most behavioral health providers do not offer both mental health and substance use disorder services.

Further, as currently drafted, the proposed standards do not examine the number of behavioral health providers serving children and adolescents. The regulations and letter to issuers should both require that plans can meet travel time and distance standards for pediatric mental health and substance use disorder care. Absent adequate networks in QHP and other private health plans, families frequently seek to enroll their child in Medicaid, which in many states offers more comprehensive behavioral health benefits. COVID-19 has been particularly hard on youth with significant increases in anxiety and depression as well as emergency room use. Networks are particularly inadequate for youth seeking mental health and substance use disorder care. For example, child and adolescent psychiatrists are very difficult to access in-network with some describing them as “unicorns.” A map of child and adolescent psychiatrists per 100,000 population shows that virtually the entire country is in an acute shortage area.⁸⁶ If HHS’s goal is to ensure that everyone has access to services, it should recognize the significant differences and even more acute shortages in behavioral health services for youth and require separate reporting of the standards for that population.

Similarly, we recommend adding a category for providers of gender-affirming surgery. While some general surgeons or plastic surgeons provide these procedures, many do not, and it can be difficult for transgender QHP enrollees to identify providers of gender-affirming surgeries. As a result, transgender QHP enrollees often become discouraged after calling multiple providers who do not offer the care they need, which also puts them at increased risk of encountering provider discrimination.⁸⁷

⁸⁶ Am. Academy Child & Adolescent Psych., *Practicing Child and Adolescent Psychiatrists* (2022), https://www.aacap.org/aacap/Advocacy/Federal_and_State_Initiatives/Workforce_Maps/Home.aspx.

⁸⁷ See Skailer R. Qvistgaard, *Testosterone and Transgender Men: The Discriminatory Impact of Testosterone's Schedule III Designation on Transgender Men Seeking Medical Care*, 13 J. HEALTH & BIOMEDICAL L. 289 (2018), <https://cpb-us-e1.wpmucdn.com/sites.suffolk.edu/dist/e/1232/files/2016/12/TESTOSTERONE-AND-TRANSGENDER-MEN.pdf>.



The proposed county-type designations for measuring time and travel distance are modeled on the Medicare Advantage network adequacy standards. We are aware that, based on population density and distribution in some states, the five designations may result in a disproportionate number of counties falling into just one or two of the county classifications and, thereby, set a very low bar for travel time/distance satisfaction with a minimal number of providers. In such cases, members would have limited access to mental health and substance use services and would have no leverage to require the inclusion of additional providers. We urge HHS to monitor whether the county designations are appropriate across the states to ensure meaningful provider availability.

Finally, HHS has asked for input on how to ensure health equity. We strongly recommend that plans be required to submit data by race and ethnicity on the population living in geographic areas that do not have access to providers within travel time and distance standards. Particularly in underserved areas that are primarily BIPOC, plans should submit plans to address the provider shortages, such as by contracting with more essential community providers.

Appointment Wait Time Standards (156.230(a)(2)(i)(B))

We also strongly support HHS's proposal to measure appointment wait times. A network adequacy standard that only evaluates the types and locations of providers may not be enough to ensure that enrollees have access to all of the essential health benefits, since in most states, providers are not obligated to provide all covered services that fall within the scope of practice of their provider license. Enrollees may not be able to access needed care due to providers' protected refusal rights. For example, if a QHP provides geographic access to OB/GYNs who provide prenatal care, but it does not contract with any providers who provide counselling and prescriptions for family planning services in its service area, enrollees will not have adequate access to those services. Similarly, in narrow networks, contracted providers may limit the number of QHP enrollees they accept in their practice as patients. The fact that a primary care provider is available a few blocks from an enrollee's home is little comfort to that enrollee if the primary care provider is not accepting new patients.

For this reason, measures of timely access to care are an important complement to provider-covered person ratios and geographic access metrics to help HHS determine with QHP networks are providing real access to the essential health benefits. We commend HHS for recognizing that both types of measures are necessary and work together to ensure that enrollees have access to covered essential health benefits. We especially commend HHS for specifying in the preamble that the “Specialty Care (non urgent)” category applies to specialty dental services provided by Standalone Dental Plans. Similarly, HHS should clarify that the “Primary Care (Routine)” category applies to routine dental services, such as regular cleanings and examinations, provided by Standalone Dental Plans. We also recommend that HHS clarify that regardless of the particular numerical standard established, in no case should a QHP enrollee have to wait longer than their provider deems clinically appropriate to access care. Thus, even if the standard set for routine specialty care is 15 business days, if a particular enrollee’s provider advises them to obtain specialty care within 5 business days, the QHP must make the necessary service available within that timeframe. This is particularly important for behavioral health services, where people often require ongoing treatment on a weekly, or even more frequent, basis.

We appreciate that HHS has identified a “short list of critical service categories” to which appointment wait times should apply. We recommend that HHS add Urgent Care to this list. The experience of people during the COVID-19 has highlighted the crucial role that Urgent Care centers provide in delivering care to people who need it quickly, but whose condition does not rise to the level of an emergency, and also in helping to make diagnostic testing and screening services available when primary care provider offices are not open. Again, we recommend that HHS clarify that Standalone Dental Plans must meet appointment wait time standards for urgent care with respect to urgent dental needs.

In addition, HHS should consider requiring plans to meet appointment wait time standards for Ancillary Services such as laboratory services, imaging, hearing services, and orthotics and prosthetics, and setting wait time standards for in-office wait time, QHP customer service phone lines.

We urge HHS to identify methods of appropriately monitoring and enforcing appointment wait time standards, which must include direct testing of QHP networks. As



the Office of Inspector General has recognized, direct testing is an important and reliable way to measure network adequacy.⁸⁸ Many states use secret shopper surveys to evaluate compliance with timely access standards.⁸⁹ Secret shopper surveys are useful because they not only capture the wait time for appointments, but can also reveal inaccuracies and limitations in plan provider directories.

Another direct testing option is to employ a standardized audit methodology that would allow QHPs to audit providers to determine whether enrollees were able to schedule appointments within the required time elapsed standards. Rather than call providers to ask about the next available appointment, QHPs would need to have a system to collect data about both when an individual requested an appointment and when the actual appointment was made. Given current data limitations, one approach to such an audit is for each QHP to ask a random selection of their network providers to track their appointments for a single day – the provider could track on an electronic or paper form the date the appointment was requested and the actual date the appointment was scheduled.

Both of these survey and audit methodologies will capture data for a single point in time, which could be skewed by seasonal variations or other temporary factors. Thus, in the long run, we encourage the HHS to work with states, QHPs, and providers to put into place data systems and mechanisms to track the date of an appointment request relative to the date for which the appointment is made, so that plans can audit the data for multiple points during the year to capture variations in seasonal availability, or calculate an average for the entire year. In addition, we encourage HHS to explore ways of tracking the sex, gender identity, race, ethnicity, sexual orientation, disability status/specific disability, and primary language of those requesting appointments as a way to identify health disparities.

⁸⁸ Off. Inspect. Gen., U.S. Dep't Health & Hum. Servs., *Access to Care: Provider Availability in Medicaid Managed Care* 13 (2014), <http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

⁸⁹ See, e.g., Simon F. Haeder et al., *Secret Shoppers Find Access To Providers And Network Accuracy Lacking For Those In Marketplace And Commercial Plans*, 35 Health Aff. 1160 (2016).

Other network adequacy standards

We urge HHS to consider additional network adequacy standards including standards for the provision of language services, cultural competency certification, auxiliary aids and services for people with disabilities, and the accessibility of services and facilities. HHS must adopt regulatory standards that account for the capacity of providers to serve limited English proficient (LEP) individuals and persons with disabilities. Large numbers of LEP individuals are purchasing insurance through the Exchanges and HHS must ensure that those QHPs offer linguistically appropriate supports. While Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act apply to QHPs, we believe HHS should adopt more explicit standards to ensure effective language services are actually provided. Similarly, Section 504 of the Rehabilitation Act and Section 1557 of the Affordable Care Act apply to QHPs but it is important for HHS to adopt more explicit standards to ensure the provision of sign language interpreters as well as other auxiliary aids and services for people with communication needs. At a minimum, HHS should require all QHP issuers to identify the linguistic and communication needs of enrollees and provide free language assistance services and auxiliary aids and services at all points of contact. For example California plans have a long standing requirement to provide enrollees with no-cost language assistance.⁹⁰ NHeLP encourages HHS to adopt additional standards to ensure that LEP enrollees and enrollees with disabilities have meaningful access to care, by adopting stronger standards to ensure that enrollees have access to oral interpreting, sign language interpreting and auxiliary aids and services and by requiring plans to report on bilingual providers and staff (discussed in the section on provider directories, above).

Further, HHS should explicitly require plans pay for interpretation services (both foreign language and sign language as needed) and auxiliary aids and services for their contracted providers. We urge HHS to require QHP issuers to arrange in their provider contracts to pay for these services directly, even in interactions between provider and patient, to ensure the availability of communication services and improve compliance by providers who often do not have the resources to evaluate or pay for competent communication services. Before any Exchange certifies a plan for participation, HHS should ensure that the Exchange requires the plan to set forth in detail its process for

⁹⁰ See Cal. Code Regs., tit. 28 § 1300.67.04(c).

paying for and guaranteeing timely communication services, both for its own customer service functions and whenever necessary to facilitate communication between enrollees and providers. These communication policies should be made available to the public on each Exchange's website.

We recommend that HHS adopt an accessibility tool to aid QHPs in assessing the accessibility of their providers to enrollees with disabilities. California has used such a tool in its Medicaid managed care program for more than a decade, and has refined the tool through multiple iterations. We recommend this tool to HHS as a starting point for evaluating and reporting on the accessibility of QHP providers to enrollees with disabilities.⁹¹

In addition, HHS should adopt minimum regulatory standards that ensure that enrollees with disabilities have full access to needed care, including any accommodations needed by people with developmental or mental disabilities. Finally, HHS should require QHPs and their providers to certify that their facilities and services are accessible to all enrollees, and fully compliant with the Americans with Disabilities Act (ADA) and other state and federal disability and civil rights laws.

HHS should especially require plans to take action to remedy any Parity Act violations. We recommend that HHS require QHPs that submit a justification for not meeting travel time and distance or appointment wait time metrics for mental health and substance use disorder providers to include (as part of the justification) its analysis that demonstrates that its network admission and adequacy practices comply with the Mental Health Parity and Addiction Equity Act. 42 U.S.C § 300gg-26(a)(8). CMS should closely scrutinize plans' parity analyses to ensure they meet the requirements of the Consolidated Appropriations Act, 2021 amendments to the Parity Act, particularly given the glaring deficiencies of recently submitted parity analyses documented in the Departments' January 2022 report to Congress.⁹² Provider shortages in mental health and substance

⁹¹ See Cal. Dept. Health Care Servs., *APL 20-006: Facility Site Review and Medical Record Review* (2020), <https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2020/APL20-006.pdf>.

⁹² Martin J. Walsh et al., Depts. Labor, Health & Hum. Servs., Treas., *2022 MHPAEA Report to Congress* (2022), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and->



use treatment networks may be an indicator that plans are not paying these providers at parity with physical health providers, have more stringent credentialing requirements for these providers, or more stringent administrative and utilization management requirements that deter some mental health and substance use providers from participating in networks.

HHS should work with QHPs and other stakeholders to encourage more integrated and comprehensive models of physical and behavioral health care in community-based settings. This should include co-located primary care and behavioral health practitioners, use of consulting psychiatrists to advise primary care practitioners on appropriate treatment, and use of peer support services. We urge HHS to begin collecting data about use of these approaches in private insurance, enabling the agency to develop future standards and payment models that encourage integrated treatment in community-based settings.

RECOMMENDATION: We suggest that HHS add a new subsections § 156.230(a)(2)(i)(C) and (D) as follows:

(C) Demonstrating that they provide timely and adequate access to language-appropriate services for limited English proficient individuals and auxiliary aids and services for people with disabilities at no additional cost to the enrollee. In accordance with guidance from HHS, QHP issuers shall assess the linguistic capacity of enrollees and shall provide free language assistance at all points of contact. QHP issuers shall also have a written policy to ensure that enrollees' language access needs are met, which shall provide for the issuers' direct payment of interpreter services; this policy shall be made available to the public on each Exchange's website.

(D) Demonstrating that they make essential health benefits are physically and programmatically accessible to enrollees with disabilities. QHP issuers shall establish written standards that comply with guidance set forth by HHS to ensure that provider facilities are physically and

[regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf](https://www.regulations.gov/document/2022-06-01/1).



programmatically accessible to people with disabilities and compliant with Section 1557 of the ACA, the Americans with Disabilities Act and any other applicable state and federal laws.

Out-of-network cost sharing (§ 156.230(e))

We urge HHS to provide clarity in this rule about QHPs obligations to their enrollees when they are unable to meet time and distance standards or appointment wait time standards. Even the most robust networks will occasionally be unable to provide extremely rare and specialized services, and may experience times when providers are temporarily unavailable, which can result in enrollees' traveling further and waiting longer to access care. We have collectively lived out this phenomenon over the last three years as many regions have experienced ongoing health care provider shortages due to COVID impacts.⁹³ Notice of appeal rights, while critical, will, all too often, provide an inadequate remedy for people with an acute need for care, such as those with mental health and substance use disorders, who cannot wait for the resolution of a complaint to get life-saving care. We urge HHS to make clear that in these situations, QHPs must hold their enrollees financially harmless for seeking care from out-of-network or higher tier providers. The promise of network adequacy is gutted by an exclusion that allows consumers to be balance billed by higher tier or out-of-network providers whom they had no choice not to use. HHS has already imposed such a requirement on emergency services.⁹⁴ Similarly, the NAIC Network Access and Adequacy Model Act includes provisions requiring insurers to prevent enrollees from being charged excess cost-sharing when services are not available in-network, and several states have adopted similar provisions.⁹⁵ HHS should also make clear that in

⁹³ See, e.g., Scott Aronson et al., Off. Ass't Sect'y Preparedness & Response, *Healthcare Provider Shortages* (2021), <https://files.asprtracie.hhs.gov/documents/healthcare-workforce-strategies-for-managing-a-surge-in-healthcare-provider-demand.pdf>; Michael Dill, *We Already Needed More Doctors. Then COVID-19 Hit*, Am. Ass'n Medical Coll. (June 17, 2021), <https://www.aamc.org/news-insights/we-already-needed-more-doctors-then-covid-19-hit>.

⁹⁴ 45 C.F.R. § 147.138(b).

⁹⁵ Nat'l Assn. Ins. Comm'rs, *Health Benefit Plan Network Access and Adequacy Model Act* § 5(C), https://content.naic.org/sites/default/files/inline-files/MDL-074_0.pdf; see also Ark. Admin. Code Rev. § 054.00.106-5(c); 19 Miss. Admin. Code Pt. 3, R. 14.5(A)(1); Mo. St. § 354.603; Neb. Rev. Stat. § 7105(1)(a);



these situations, QHPs have an obligation to assist their enrollees in identifying an appropriate provider, and executing a single-case agreement if possible. Again, the NAIC Network Access and Adequacy Model Act would require plans to arrange for the provision of covered services by out-of-network providers when the service is not available in-network, as do several states.⁹⁶ Moreover, changes to this section are necessary to ensure compliance with the No Surprises Act.

In addition, QHPs that are unable to meet geographic access standards should be encouraged to provide regularly scheduled or as-needed transportation from areas within a designated area to network primary care providers, hospitals, and clinics, as necessary to ensure that such facilities remain reasonably accessible. Further, Exchanges should urge these QHPs to dispatch mobile health care vans to locations within the designated area at regular scheduled times, at least quarterly, or more frequently if medically necessary.

RECOMMENDATION: We suggest that HHS amend § 156.230(e) as follows:

(e) Out-of-network cost sharing. Beginning for the 2018~~23~~ and later benefit years, for a network to be deemed adequate, each QHP that uses a provider network must:

(1) ~~Notwithstanding § 156.130(c), count the cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting towards the enrollee's annual limitation on cost sharing; or~~

(2) ~~Provide a written notice to the enrollee by the longer of when the issuer would typically respond to a prior authorization request timely submitted, or 48 hours before the provision of the benefit, that additional costs may be incurred for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.~~**any other provision, in any instance**

N.H. Code Admin. R. Ins. § 2701.04(d); and S.D. Stat. § 58-17F-6.

⁹⁶ Nat'l Assn. Ins. Comm'nrs, *supra* note 95; see also Cal. Code Regs., tit. 28, § 1300.67.2.2(c)(7)(B); Colo. Rev. Stat. Ann. § 10-16-704(2)(a); 50 Ill. Admin. Code § 2051.310(a)(6)(H)-(I); Wash. Admin. Code § 284-170-200(5).



where a QHP cannot comply with network adequacy standards including time and distance or appointment wait time standards for any essential health benefit within the first cost-sharing tier, the QHP must arrange for the participant, beneficiary, or enrollee to obtain the benefit from a provider in a higher network tier or out-of-network as expeditiously as possible;

(2) Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network or higher tier service provided when that benefit is not available in the QHP's first cost-sharing tier cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the benefit were provided in-network in the first cost-sharing tier; and

(2) QHPs must not impose any balance billing prohibited by the No Surprises Act.

Telehealth

We support HHS's proposal to require all issuers seeking certification of plans to be offered as QHPs through the FFE to submit information about whether network providers offer telehealth services. We encourage HHS to collect not only information about whether QHP providers offer services by telehealth directly, but also to collect information about which services are being delivered by telehealth versus in person, what telehealth modalities are used (e.g., audio/visual, audio only, asynchronous), and other ways that telehealth is being used in QHP systems, such as to increase the availability of provider-to-provider consultation.

Given the rapid growth of telehealth over the last three years, and the need for more information about when telehealth can most effectively deliver services to QHP enrollees, we encourage HHS to refrain from aligning the FFE network adequacy standards with Medicare Advantage's telehealth approach (in which issuers are offered a credit towards meeting time and distance standards) at this time. Not yet permitting QHP issuers to "count" telehealth providers toward meeting network adequacy standards is especially important since many key demographic groups of QHP enrollees face barriers to effective access to services by telehealth. For example, lower-income



enrollees and those in rural areas in particular often face multiple challenges to accessing services by telehealth including unreliable broadband access, and limited cell phone plans.⁹⁷ Further, some telehealth modalities are not readily accessible to people with disabilities, and individuals who are LEP.⁹⁸ Thus, HHS must affirm that QHP enrollees always have the right and ability to access care in-person, even if a service is available via telehealth, to ensure that people are able to most effectively access the care they need. Reflecting the importance of providing an in-person option, HHS should not credit telehealth providers toward time and distance standards at this time.

We acknowledge that the tension between provider shortages and the ease of telehealth is very real, particularly in rural communities and for specialized health services. The use of telehealth should not undermine network adequacy and other managed care protections. However, in cases where provider shortages exist and telehealth is necessary to ensure access to care, HHS should clearly define any exceptions to its network adequacy standards, including types of providers and/or instances where telehealth-only visits can be provided. The list should be carefully curated and updated regularly to reflect changes in workforce including the availability of multicultural, multilingual providers, and state licensure requirements.

In addition, we encourage HHS to monitor the role that “telehealth-only” providers or “third-party telehealth providers” without a physical location play in QHP networks. We encourage HHS to require such providers to register with HHS and submit annual data reports showing utilization and encounters among QHP enrollees. HHS should prohibit plans from meeting network adequacy requirements through significant reliance on services offered via telehealth only or third-party telehealth providers. Use of telehealth only or third party telehealth providers pose important concerns regarding care coordination and care management. It is not clear, for example, how telehealth-only providers will be able to connect patients with local, in-person providers, especially with regards to referrals for clinical care, integration within a continuum of care, and health related social needs more broadly. We strongly support more careful monitoring of

⁹⁷ See, e.g., Dan Young et al., NAT’L HEALTH LAW PROG., *Expanding Telehealth Under COVID-19: Supporting Access to Care* (2020), <https://healthlaw.org/expanding-telehealth-under-covid-19-supporting-access-to-care>.

⁹⁸ *Id.*; see also Aswita Tan-McGrory et al., Addressing Virtual Care Disparities for Patients with Limited English Proficiency 28 AM. J. MANAGED CARE 36 (2022).

these types of telehealth services and would urge HHS to engage in frequent monitoring.

Essential Community Providers (§ 156.235)

HHS proposes that for PY (Plan Year) 2023 and beyond, the required ECP provider participation standard be raised from 20 percent to 35 percent of available ECPs based on the applicable PY HHS ECP list, including approved ECP write-ins that would also count toward a QHP issuer's satisfaction of the 35 percent threshold. We generally support this proposal, and propose some modifications to better ensure that QHP enrollees, especially those who have low-incomes and those who are Black, Indigenous and People of Color (BIPOC) have full access to essential health benefits.

Require QHPs to meet the 35 Percent Threshold for each ECP category (§ 156.235(a)(2)(i) & (b)(i))

Including Essential Community Providers (ECPs) who provide care to predominately low-income and medically underserved populations in QHP networks is key to improving health outcomes and health equity.⁹⁹ QHPs serve large numbers of people capable of becoming pregnant, so it is also crucially important that HHS ensures that their networks include ECPs that can serve the unique health needs of these individuals. Furthermore, including a significant number of safety net providers within every network is essential to better birth outcomes. BIPOC people face significant barriers in access to and utilization of care.¹⁰⁰ Nonelderly BIPOC individuals face increased barriers to accessing care compared to whites and have lower utilization of care. For example, preterm birth rate for Black people is 51 percent higher than the rate among people of other races, and Black people also experience higher rates of certain chronic conditions such as diabetes, hypertension, and sexually transmitted infections,

⁹⁹ Cristina Jade Peña *et. al.*, Kaiser Family Found., *Federal and State Standards for “Essential Community Providers” under the ACA and Implications for Women’s Health* (2015), <http://files.kff.org/attachment/issue-brief-federal-and-state-standards-for-essential-community-providers-under-the-aca-and-implications-for-womens-health>.

¹⁰⁰ Samantha Artiga & Kendal Orgera, Kaiser Family Found., *Key Facts on Health and Health Care by Race and Ethnicity* (2019), <https://www.kff.org/report-section/key-facts-on-health-and-health-care-by-race-and-ethnicity-coverage-access-to-and-use-of-care>.

which can result in poor birth outcomes if unidentified or unmanaged before pregnancy.¹⁰¹ Increasing ECP participation in QHPs is an important step toward addressing these disparities.

For this reason, we urge HHS to amend the regulatory text to require QHPs to include 35 percent of available QHPs in their networks. We continue to support HHS decision to treat multiple providers at a single location as one ECP, and to require QHPs with tiered networks to meet the ECP threshold in the lowest cost-sharing tier.

RECOMMENDATION: We suggest that HHS amend §§ 156.235(a)(2)(i) and (b)(2)(i) as follows:

(a)(2)(i) The network includes as participating providers at least ~~a minimum~~ **thirty-five (35)** percentage, ~~as specified by HHS,~~

...

(b)(2)(i) (i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a ~~minimum~~ **thirty-five (35)** percentage, ~~as specified by HHS,~~ . . .

Clarify the requirements for “Other ECP Providers” and expanding that category (§ 156.235(a)(2)(ii) & (b)(2)(ii))

In the preamble, HHS has requested input on whether it should consider non-substantive revisions to this section to clarify that the requirement that QHPs offer contracts to at least one ECP in each of the categories for each county in the service area. We support clarification, and also urge HHS to require QHPs to offer contracts to each of the ECP types that fall within the category of “Other ECP Providers,” since these provider types are quite distinct (a hemophilia treatment center cannot substitute for an STD clinic). In addition, we recommend that HHS add a requirement that QHPs demonstrate that they can meet the 35 percent participation threshold for each ECP category, rather than across all types of ECPs. The current measure lumps all of the

¹⁰¹ March of Dimes, *2021 March of Dimes Report Card 2* (2021), https://www.marchofdimes.org/materials/March_of_Dimes_US_2021_Report_Card_11152021.pdf.

ECP types together, which could easily result in an uneven distribution of ECP types within a plan's network that hinders access to care. To this end, the 35 percent threshold should also be applied to each of the ECP types that fall within the category of "Other ECP Providers," since, again, these provider types are quite different.

HHS also seeks feedback on whether it should define the category of "Other ECP Providers" in the regulatory text. We urge HHS to do so, and support the addition of "Substance Use Disorder Treatment Centers" to this category. We also suggest that HHS add the category of "Freestanding Birth Centers" to the other ECP category, as this is a crucial service for pregnant enrollees. The Strong Start for Mothers and Newborn Initiative, which concluded in 2018, found "significantly improved outcomes" for participants who gave birth at freestanding birth centers (as opposed to receiving care at maternity care homes or group prenatal care).¹⁰²

In addition, NHeLP requests that HHS strengthen the ECP standard by requiring issuers to make good faith efforts to contract with at least one ECP in each category for each geographic region it services. Since the goal of the ECP requirement is to ensure that consumers have meaningful access to these providers, we urge HHS to adopt a strong standard that requires issuers to make reasonable efforts to actually include at least one ECP in each category in each covered region.

NHeLP understands that there may be rare cases where QHP issuers are not able to reach an agreement with any ECPs in a particular category in a particular region. To address these cases, we urge HHS to explicitly incorporate a good faith standard to ensure that QHP issuers have made real efforts to establish contracts with ECPs. We support the language HHS has included in previous guidance specifying that to be considered a good faith offer, a contract must offer rates and contract provisions that a

¹⁰² Adam Boehler & Mary C. Mayhew, Ctr. Medicaid & Medicare Servs., *Joint Informational Bulletin: Strong Start for Mothers and Newborns initiative (Strong Start)* (Nov. 9, 2018), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib110918.pdf>; see also Embry Howell et al., *Potential Medicaid Cost Savings from Maternity Care Based at a Freestanding Birth Center*, 4 Medicare & Medicaid Res. Rev. E1 (2014), https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a06.pdf.

“willing, similarly situated non-ECP provider would accept or has accepted.”¹⁰³ We urge HHS to include language in the regulation specifying that good faith contract terms must include all of the services the plan covers and the ECP provides and include reimbursement at generally applicable payment rates. We are concerned that without additional specificity, issuers will continue to use a low-reimbursing contract as verification, forcing ECPs into lower reimbursement rate contracts. Without a strong requirement that QHPs make real efforts to establish legal agreements, the overall goal of the guidance will be eroded and QHP issuers will be able to evade the ECP standard by offering ECPs contracts but not following through on them. Moreover, HHS should encourage Exchanges to look closely at any QHP issuer that lacks contracts with ECPs, as that fact alone raises an inference that the issuer’s offers have not been made in good faith.

RECOMMENDATION: We suggest that HHS amend § 156.235(a)(2)(ii) & (b)(2)(ii) as follows:

- (a)(2)(ii) The issuer of the plan ***makes good faith*** offers ***of*** contracts, ***considering generally applicable payment rates and contract provisions that a willing, similarly situated non-ECP provider with median rates would accept or has accepted*** to—
 - (A) All available Indian health care providers in the service area, applying the special terms and conditions required by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health care providers developed by HHS; and
 - (B) At least one ECP in each of the ECP categories (Federally Qualified Health Centers, Ryan White Providers, Family Planning Providers, Indian Health Care Providers, Hospitals, ***STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, Community Mental Health Centers, Rural Health Clinics, Substance Use Disorder Treatment Centers, Freestanding Birth Centers, and other entities that serve predominantly***

¹⁰³ See, e.g., Cts. Medicare & Medicaid Servs., *Frequently Asked Questions on Essential Community Providers* 4 (2014), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-on-ECPs-6-12-14.pdf>.

low-income, medically underserved individuals and other ECP providers) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. ***In addition, the network must include as participating providers at least thirty-five (35) percent of available essential community providers in each plan's service area for each ECP category.***

...

(b)(2)(ii) The issuer's integrated delivery system provides all of the categories of services provided by entities in each of the ECP categories (***Federally Qualified Health Centers, Ryan White Providers, Family Planning Providers, Indian Health Care Providers, Hospitals, STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, Community Mental Health Centers, Rural Health Clinics, Substance Use Disorder Treatment Centers, Freestanding Birth Centers, and other entities that serve predominantly low-income, medically underserved individuals***) in each county in the plan's service area as outlined in the general ECP standard, or otherwise ***makes good faith*** offers of a contract, ***considering generally applicable payment rates and contract provisions that a willing, similarly situated non-ECP provider with median rates would accept or has accepted***, to at least one ECP outside of the issuer's integrated delivery system per ECP category in each county in the plan's service area that can provide those services to low-income, medically underserved individuals. ***In addition, the network must include as participating providers at least thirty-five (35) percent of available essential community providers in each plan's service area for each ECP category.***

ECP write-in option (§ 156.235(a)(3) & (b)(3))

In addition, HHS states that it will continue to allow issuers to use the ECP write-in process to identify ECPs that are not on the HHS list of available ECPs. We urge HHS to eliminate this option that permits issuers to forgo the ECP standard completely by submitting a narrative justification that describes why they could not meet the standard



but still have a network that is sufficient to meet the needs of low-income and underserved enrollees. This provision has the potential to become the exception that swallows the rule. Without an adequate number of ECPs in an issuer's network, people who rely on ECPs for their care will have less access to the care they need. Given the importance of including ECPs in QHP networks, HHS should not provide issuers with leeway to avoid meeting its ECP standards.

RECOMMENDATION: We suggest that HHS eliminate §§ 156.235(a)(3) and 156.235(b)(3).

Other considerations regarding ECPs

We again acknowledge that the tension between provider shortages and the ease of telehealth is very real, particularly in rural communities and for specialized health services. The use of telehealth should not undermine ECP and other access to care protections. Rather, HHS should encourage QHPs to consider telehealth as another tool in which to improve access while emphasizing that telehealth cannot replace in person health care. We acknowledge that many ECPs including FQHCs and family planning providers have offered critical services during the pandemic using telehealth, but emphasize that ultimately, the modality of service (whether it is telehealth or in-person) must be dictated by the patient's preference and best interests.

We also note here that HHS should ensure that QHP issuers rigorously monitor and enforce ECP participation in their networks. HHS should require QHPs to comply with monitoring and enforcement policies that ensure adequate oversight of QHP networks' compliance with ECP standards throughout the coverage year. We recommend that HHS require issuers to report any material changes to their ECP contracts within 30 days, and ensure that at no time their network falls below the ECP minimum standards. We urge HHS to require Exchanges to consider access to ECPs in any monitoring and enforcement that it undertakes related to network adequacy as a whole, in addition to monitoring for compliance with ECP standards separately.

Quality Standards: Quality Improvement Strategy (§ 156.1130)

The proposed rule would require all Qualified Health Plans(QHPs) with at least two consecutive years in a market to include in their quality improvement strategies (QIS) at least one payment structure that provides financial incentives for activities aimed at reducing health and health care disparities. We support this policy change as an initial step, but ask CMS to require more public transparency and accountability about the process of selecting, implementing, evaluating, and reporting the outcomes of QIS interventions.

Over the long term, one way to drive attention and innovation to reduce health and health care inequities is to tie those outcomes to payment. This policy change ensures that QHPs (and their network providers) prioritize health equity work. That said, we believe this proposal does not go far enough to ensure that QHPs will take the necessary steps to create effective interventions targeted at the key areas of need for their enrollees from underserved communities.

Under current regulations, which CMS does not propose to change, there are no public reporting requirements for QIS activities at all. We could not even find a list of QIS topics selected by QHPs for prior plan years, let alone a public report on their progress or successful outcomes.

In Medicaid managed care, External Quality Review requires plans to implement and report on Performance Improvement Projects (PIPs) as part of their quality and performance improvement programs. States contract with EQR organizations to validate and publicly report on PIP results annually, and states must outline any mandated PIP topics in their state quality strategies. Such transparency allows the public to see both what states and plans choose to prioritize and whether those efforts bear any fruit.

With this degree of public transparency in Medicaid, we have found that many PIPs are poorly organized, fail to create adequate baseline data, and/or have little positive impact on improving outcomes. For example, Minnesota required Medicaid plans to conduct and report on three-year PIP to improve racial and ethnic disparities in depression

management.¹⁰⁴ The results were disappointing. Of eight participating plans, two showed markedly worse disparities after three years, three more showed little change in overall rates or disparities, two did not disaggregate their data by race, and the last two did not report or had too small a data sample.¹⁰⁵ Only one of eight plans reported an increase in depression management that met its stated goals, and that plan did not disaggregate the outcome by race.¹⁰⁶

Still, we can draw lessons from this apparently unsuccessful PIP that could help to inform QHP QIS policy. First, the EQR reporting requirements allow the public to see which efforts succeed and which fail, and so to hold plans and states accountable for their results. Second, state quality strategies are open to public comment and so allow stakeholders to weigh in on quality improvement priorities.¹⁰⁷ Third, we believe one reason the PIP process has such uneven results in Medicaid is due to a lack of clear consequences for poor outcomes. Few PIPs are tied directly to financial rewards or penalties.

The proposed QIS policy does tie effective performance on reducing health and health care inequities to financial reward, but it lacks the first two elements: first, QHPs should have to seek input from underserved enrollees or stakeholders who represent underserved communities to guide their QIS activity selection – to shape which activities related to health or health care inequities they prioritize. Second, more public accountability is necessary to reassure the public that issuers (and CMS) take these initiatives seriously.

We recommend that CMS add these public accountability improvements to the regulation at § 156.1130, in addition to the proposed requirement that plans develop at least one payment structure aimed at reducing health inequity in their quality improvement strategy.

¹⁰⁴ Island Peer Review Org. [“IPRO”], *Minnesota EQR Technical Report 2017*, 15 (Apr. 2019), <https://edocs.dhs.state.mn.us/lfservlet/Public/DHS-6888E-ENG>. Blue Plus showed an increasing disparity of 8 percentage points over 3 years. Hennepin Health showed an increase of 14.3 percentage points over the same period.

¹⁰⁵ *Id.* at 18, 31, 43, 55, 66, 75, and 89.

¹⁰⁶ *Id.* at 89.

¹⁰⁷ 42 C.F.R. § 438.340(c)(1).

Medical Loss Ratio (§ 158.150)

Insurers that have failed to spend at least the required amount of premium revenue on clinical services versus administrative expenses must rebate enrollees. In 2020 and 2021, these rebates have exceeded \$2 billion. CMS identifies egregious examples of insurers using various tactics to avoid paying rebates owed to consumers. For example, some bonuses to providers are triggered only when the MLR rebate provision is triggered – meaning they relate to the insurers' finances, not provider performance – inflating claims by as much as 30 to 40 percent. Also, insurers have attributed indirect expenses to quality improvement expenses – including the purchase of artwork and travel and entertainment expenses – to inflate health spending and deprive consumers of rebates. Limiting the definition of a quality improvement activity to include only direct expenses related to clear quality or clinical standards is both appropriate and necessary.

Solicitation of Comments – Choice Architecture and Preventing Plan Choice Overload

HHS is correct to be concerned that consumers have too many plan choices on the federal and state Exchanges. In recent years, there has been a sharp increase in the number of plans available to consumers. In 2019, in the FFEs and SBE-FPs, an average of 27.1 plans were available per enrollee.¹⁰⁸ This number climbed to 109.2 plans per enrollee in 2022.¹⁰⁹

A recent RAND Corporation study shows that when consumers are given too many plan choices, there is the potential to make poor enrollment decisions. Multiple factors result in less than optimal plan choice decision making, including but not limited to the challenge of processing complex health plan information, inadequate decision support tools, and low health literacy and numeracy.¹¹⁰ Consumers may incorrectly calculate costs, or focus on premiums without even considering total out-of-pocket costs. When

¹⁰⁸ HHS Notice of Benefit and Payment Parameters for 2023, 87 Fed. Reg. 584, 690 (proposed Jan. 5, 2022) (to be codified at 45 C.F.R. pts. 144, 147, 153, 155, 156, 158).

¹⁰⁹ *Id.*

¹¹⁰ Erin Audrey Taylor et al., *Consumer Decisionmaking in the Health Care Marketplace*, RAND Corp. (2016), https://www.rand.org/pubs/research_reports/RR1567.html.



there are too many options, consumers may also be susceptible to how choices are presented on the website. For example, someone might select a plan merely because it is presented first on the website. Of most concern, consumers may experience decision fatigue and not enroll in health insurance at all.

In an effort to simplify the plan choice decision making process, NHeLP supports efforts to standardize plans. Consumers are able to compare plans more easily based on premium price, provider network, and plan quality when plan options are standardized. (See comments above in section 156.201).

The literature suggests that plan choice decision making can be improved by limiting the number of plans available to consumers. Therefore, NHeLP supports HHS' future efforts to limit the number of non-standardized plans that issuers can offer through the FFEs and SBE-FPs. Another viable option to limit the number of plans is to resume the meaningful difference standard that was previously codified at 45 C.F.R. § 156.298. This would limit the volume of nearly similar plans so that consumers can readily compare plan choices and make good consumer choices. These strategies are particularly important now that the number of plans offered through the Exchanges have significantly increased.

HHS should mandate reform of Exchange choice architecture. For one, both federal and state Exchanges should be required to implement decision-support tools that direct consumers to contemplate total costs instead of just premiums. One such example is the use of "shop and compare" tools. Second, Exchanges should be required to meet basic Exchange design standards so that consumers can sort and filter plans based on key characteristics like total cost, provider network, and plan quality. Third, Exchange websites need to limit the use of jargon and complex health terms.

Further, Exchanges should be required to actively redirect consumers to superior plans, which we define as plans that are cheaper but have a higher actuarial value (AV). These are situations where consumers have made clear choice errors by selecting a suboptimal plan. Federal and state Exchanges could include pop-up alerts and require a consumer to click to confirm a choice when it is an explicitly inferior plan, and the consumer will pay more for a lower AV. Connecticut's SBM implemented these steps and it led to a decrease in individuals below 200 percent FPL choosing non-CSR

plans.¹¹¹ NHeLP also supports the more aggressive option of affirmatively suppressing inferior plans, and automatically transitioning consumers to superior plans. For example, the Exchange could transition individuals from bronze to silver plans if consumers are otherwise eligible for these silver products and it will be no additional cost to the consumer. Covered California has implemented one such policy that automatically transitions individuals at or below 150 percent of the federal poverty level (FPL) into a product with the same carrier if they are eligible for a zero dollar premium.

In addition to reforming choice architecture and limiting plan selection, the evidence shows that outreach efforts help optimize plan selection and help consumers avoid choice errors. A Covered California analysis found that nearly 20,000 Covered California consumers selected more expensive gold and platinum plans in 2019 despite being eligible for a less expensive enhanced silver plan with richer benefits.¹¹² The Exchange sent additional emails and letters to these consumers describing the financial savings if they switched to the silver product, and as a result, roughly 20 percent of these individuals switched to a silver plan with a lower premium and cost-sharing savings.¹¹³ This analysis clarifies that consumers make suboptimal plan selections simply because of the sheer number of plans to choose from, and the complexity of information on Exchange platforms. HHS should require Exchanges to implement a multi-pronged approach to helping consumers navigate the Exchange platforms to make sound plan selections.

Solicitation of Comments Regarding Health Equity, Climate Health, and Qualified Health Plans

We support HHS's commitment to advance health equity across its marketplace programs and activities. As a primary measure to accomplish this goal, HHS should require standardized demographic data collection practices for QHPs and marketplaces, including SBEs and HealthCare.gov. Through improved data collection, HHS can

¹¹¹ David Anderson et al., *How To Improve Consumer Plan Selection In ACA Marketplaces – Part 1*, Health Affs. Forefront (last visited Jan. 23, 2022), <https://www.healthaffairs.org/doi/10.1377/forefront.20210602.199820/full/>.

¹¹² Andrew Feher & Isaac Menashe, *Using Email and Letters To Reduce Choice Errors Among ACA Marketplace Enrollees*, Health Affs. 812, 814 (May 2021), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2020.02099>

¹¹³ *Id.* at 815.



increase oversight and monitoring of health disparities and target interventions that appropriately address identified inequities.

Health equity is achieved when a person's characteristics and circumstances do not predict their health outcomes. High quality, disaggregated data on enrollee demographics are necessary to monitor progress toward this goal. As it became clear during the COVID-19 pandemic, health care access, treatment and outcomes vary by characteristics such as race, ethnicity, and socioeconomic status.¹¹⁴ Without disaggregated demographic data, health disparities remain hidden, discrimination persists, and corrective interventions are near impossible to accurately design. Comprehensive data collection can also assist QHPs in planning and providing logistical support to enrollees by ensuring access needs are met, such as auxiliary aids and services, language services, and use of appropriate name and pronouns. Ultimately, data collection advances both quality and equity of care.

We recommend that HHS require QHPs to collect and report data on enrollee demographic identifiers, including race, ethnicity, primary language, sex, sexual orientation, gender identity, and disabilities. HHS should adopt standardized language and definitions for demographic identifiers using information gathered from prior interagency studies and expert recommendations. Racial, ethnic, and primary language data should be collected at a granular level to allow for disaggregation of distinct groups, and HHS should work with stakeholders to ensure appropriate representation. HHS should work with QHPs to ensure that data can be stratified by sub-populations that might experience multiple barriers to care.¹¹⁵

Many resources already exist, including within HHS, that can inform HHS's data collection standards. As a few examples, the Institute of Medicine's 2009 recommendations on collecting race, ethnicity, and primary language data are often cited,¹¹⁶ as are their recommendations for collecting SOGI data through the Electronic

¹¹⁴ Sarah Miller, Laura R. Wherry, and Bhashkar Mazumder, *Estimated Mortality Increases During the COVID-19 Pandemic by Socioeconomic Status, Race, and Ethnicity*, Health Affairs (Jul. 21, 2021), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.00414>.

¹¹⁵ That is, when looking at disaggregated demographic identifiers of enrollees, analysts should be able to see outcomes not just by race or gender, but also by race and gender, for example.

¹¹⁶ Cheryl Ulmer, Bernadette McFadden, and David R. Nerenz, Eds., Subcommittee on Standardized Collection of Race/Ethnicity Data for Healthcare Quality Improvement, *Race,*

Health Record (EHR). The Williams Institute published several reports and recommendations on how to collect SOGI data through surveys.¹¹⁷ HHS commissioned a report on disability data collection that provides an overview of research on data collection modes, measurement, strategies, adaptive technologies, questionnaire design, and more.¹¹⁸ The HHS Office of Minority Health recently updated its data collection standards and recommendations from the 1997 OMB standards to include collection of sex and disability status identifiers.¹¹⁹ HHS should build on these existing resources by conducting additional review and seeking stakeholder input before adopting final standards.

HHS has requested comment on potential challenges to data collection. A low response rate threatens the usefulness of any data collection requirement. Low participation may result from lack of enrollee responses, or it may result from lack of adherence to data collection and reporting requirements by those tasked with collecting responses. For many enrollees, demographic identifiers can be sensitive information that they may decline to share. QHP employees may lack the training necessary to engage with sensitive topics, especially at points of contact outside of patient care. Enrollees may lack trust in the health system, worry about data privacy, misunderstand what is being

Ethnicity, and Language Data: Standardization for Health Care Quality Improvement, Institute of Medicine (2009), <https://www.ahrq.gov/research/findings/final-reports/iomracereport/index.html>.

¹¹⁷ Sexual Minority Assessment Research Team, *Best Practices for Asking Questions about Sexual Orientation on Surveys*, The Williams Institute (2009), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Best-Practices-SO-Surveys-Nov-2009.pdf>; Gender Identity in U.S. Surveillance (GenIUSS) Team, *Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys*, The Williams Institute (2014), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Survey-Measures-Trans-GenIUSS-Sep-2014.pdf>.

¹¹⁸ Jason Markesich, Stacie Feldman, and William Rafferty, *2020 Compendium of Disability Data Collection Methods*, Mathematica (2020), <https://mathematica.org/publications/2020-compendium-of-disability-data-collection-methods>.

¹¹⁹ Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status, OMH (2018), <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53>; and see HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status, ASPE, (2011), <https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0>.



asked, or refuse to participate for other reasons.¹²⁰ Yet without enrollee participation, QHPs cannot gather a complete or accurate picture of health disparities.

Historically, HHS has seen low response rates for required demographic reporting, and should take action to ensure the success of any new data collection requirement.¹²¹ We recommend that HHS address this challenge by providing the following supports for QHPs and issuers: First, HHS should solicit expert recommendations, review prior studies, and engage stakeholder input to ensure appropriate language and demographic identifiers are selected as standard reporting requirements. Low responses may result from use of outdated or offensive language or failure to recognize significant populations.¹²² HHS can foster trust and participation by engaging input of stakeholder groups in the process of creating data collection practices.

Second, HHS should provide research-informed guidance to QHPs on best practices for collecting data from enrollees. HHS should conduct a review of scientific literature and prior studies of effective survey models and communication practices that generate valid and accurate responses. While HHS should require QHPs to collect certain demographic identifiers, HHS should ensure that enrollees will not be penalized for failing to provide information; that is, plans should be required to ask enrollees for their demographic data but it must remain optional for enrollees to provide. HHS should support QHPs in adopting practices that allow enrollees to voluntarily self-report demographic identifiers, for example, on a self-administered survey where appropriate.¹²³ The Health Research and Educational Trust (HRET) developed a toolkit

¹²⁰ See Elizabeth Lunkenen and Emily Zylla, *Exploring Strategies to Fill Gaps in Medicaid Race, Ethnicity, and Language Data*, SHADAC (2020), <https://www.shvs.org/exploring-strategies-to-fill-gaps-in-medicaid-race-ethnicity-and-language-data/>.

¹²¹ See *Race/Ethnicity Data in CMS Medicaid (T-MSIS) Analytic Files Updated December 2021 – Features 2019 Data*, SHADAC, <https://www.shadac.org/news/raceethnicity-data-cms-medicaid-t-msis-analytic-files-updated-december-2021-%E2%80%93-features-2019>; Nancy Krieger, Gregg Gonsalves, Mary T. Bassett, William Hanage, Harlan M. Krumholz, *The Fierce Urgency of Now: Closing Glaring Gaps in US Surveillance Data on COVID-19*, Health Affairs (Apr. 14, 2020), <https://www.healthaffairs.org/doi/10.1377/forefront.20200414.238084/full/>.

¹²² See *Collection of Sexual Orientation and Gender Identity (SOGI) Data*, SHADAC (2021), https://www.shvs.org/wp-content/uploads/2021/10/SOGI-Data-Collection-in-Medicaid_SHVS-Issue-Brief_Revised.pdf.

¹²³ See, e.g., Sexual Minority Assessment Research Team, *Best Practices for Asking Questions about Sexual Orientation on Surveys*, The Williams Institute (2009),

for collecting race, ethnicity, and primary language data in hospitals after testing different rationales.¹²⁴ HHS should undertake similar testing of rationales and development of training toolkits that would be made available to address all demographic identifiers adopted by HHS.

Third, HHS must continue to ensure that data collected is maintained securely by QHPs and associated entities. Enrollees must feel comfortable disclosing personal identifying information in order for data collection to be effective. Thus, strict standards must be adopted to ensure that data cannot be used for negative actions such as immigration or law enforcement, redlining, or other invidious discrimination. Communication from HHS and QHPs should make enrollees aware of their privacy protections and rights, including those granted under the ACA and state law. Enrollees should be informed of the purpose of data collection and who will have access to any personal identifying information.

Fourth, as part of any new data collection requirement, HHS should actively provide QHPs with resources to help them obtain quality data for both monitoring and logistical purposes, including any toolkits and resources developed through additional research. Beyond guidance and suggestions for best practices, HHS must affirmatively support QHPs with ongoing training and technical assistance to ensure that data is valid, reliable, and serves the purpose of exposing the existence of inequities.

Finally, to foster ongoing trust in its commitment to health equity, HHS must require that QHPs routinely analyze enrollee demographic data to identify health disparities and implement corrective action. HHS may enforce this obligation by adopting the HEA requirement discussed below. HHS should, however, retain additional oversight over QHPs' use of disparity data to correct health inequities by monitoring corrective action plans, providing resources, and ensuring transparency.

<https://williamsinstitute.law.ucla.edu/wp-content/uploads/Best-Practices-SO-Surveys-Nov-2009.pdf>.

¹²⁴ Romana Hasnain- Wynia, Debbie Pierce, Ahmed Haque, Cynthia Hedges Greising, Vera Prince, and Jennifer Reiter, *Health Research and Educational Trust Disparities Toolkit*, American Hospital Association (2007), <https://ifdhe.aha.org/hretdisparities/toolkit>.



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

We also recommend that HHS set an example by improving data collection in its own programs and activities, such as collecting comprehensive demographic data in HealthCare.gov and requiring SBEs to do the same. Currently, HealthCare.gov only collects sex, race and ethnicity from all applicants along with one disability-related question. It collects language data only from the household contact, who may not even be an enrollee, and fails to collect any data on sexual orientation and gender identity.¹²⁵ Improvements in collecting demographic data on applications will not likely alleviate the need for QHPs to also collect this data, particularly because some individuals will be more confident providing demographic data to a plan or provider (who shares it with a QHP) as opposed to a government agency to enroll in a program, but will demonstrate HHS' own commitment to collecting and utilizing demographic data to address health disparities and improve health equity.

Length of Comment Period

We wanted to raise concerns regarding the short 30 day comment period and designation of the comment period beginning from the posting of the public inspection version of the NPRM as opposed to its formal publication in the Federal Register. These practices undermines the intent and purpose of the Administrative Procedure Act and are not consumer friendly.

¹²⁵ HHS previously explored adding gender identity questions to the federal Marketplace applications, but has not yet implemented this plan. See LGBT Policy Coordinating Committee, Advancing LGBT Health and Well-being: 2016 Report, U.S. Dep't of Health & Human Svcs., at 6 (2016), <https://www.hhs.gov/sites/default/files/2016-report-with-cover.pdf>.

We strongly urge HHS to return to longer comment periods. A 30 day period is incredibly challenging for individuals and organizations to respond to effectively. The public often does not have advance notice of a NPRM, and because the comment period includes weekends and sometimes holidays, a 30-day comment period taxes the resources of individuals and organizations to digest, analyze, confer, and draft comments. This problem is compounded when the proposed rule is particularly complex, as is the case here. While we recognize the time constraints HHS often operates under, it is essential that HHS benefit from the detailed analysis and input of the public. With the quantity of rulemaking many organizations seek to respond to, the repetitive “sprint” of a 30-day comment period increases the workload of organizations, and particularly smaller organizations, to effectively respond. We have heard of organizations opting out of commenting because of short comment periods.

Further, HHS has increasingly started the public comment period on the date of public inspection rather than the date of formal publication in the Federal Register. We believe this contravenes the requirements of the Administrative Procedure Act, 5 U.S.C. § 553(b), (c) (generally requiring publication in the Federal Register and public comment “[a]fter notice required by this section”). In addition, this practice greatly disadvantages the public at large, which is unlikely to know how to access public inspection documents. This is particularly unfair when documents have been on public inspection for multiple days prior to formal publication. Further, the layout of public inspection documents – often double-spaced and running hundreds of pages -- is often difficult and burdensome to review. Starting the clock at public inspection rather than Federal Register publication reduces the ability for HHS to benefit from an informed comment period.

As an organization that routinely comments on HHS proposed regulations and assists other organizations and individuals in commenting (e.g., by preparing template comments and comment portals), our direct experience is that short comment periods impede everyone’s ability to conduct a comprehensive assessment and provide a full analysis.



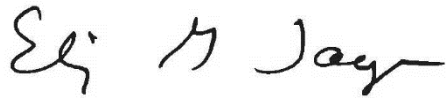
We hope that future HHS rulemaking throughout the agency will resume counting the public comment period from the date of publication in the Federal Register as well as embrace longer comment periods.

Conclusion

Thank you for the opportunity to comment on this important issue. Our comments include citations to supporting research and documents for the benefit of HHS in reviewing our comments. We direct HHS to each of the items cited and made available to the agency through active hyperlinks, and we request that HHS consider these, along with the full text of our comments, part of the formal administrative record on this proposed rule.

If you have any questions about our comments, please contact Mara Youdelman at (202) 683-1999 or youdelman@healthlaw.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth G. Taylor".

Elizabeth G. Taylor
Executive Director

