



Elizabeth G. Taylor
Executive Director

Board of Directors

Ann Kappler
Chair
Prudential Financial, Inc.

William B. Schultz
Vice Chair
Zuckerman Spaeder LLP

Shamina Sneed
Secretary
TCW Group, Inc.

Nick Smirensky, CFA
Treasurer
New York State Health Foundation

L.D. Britt, MD, MPH
Eastern Virginia Medical School

Jeanna Cullins
Fiduciary & Governance Practice Leader
(Ret.)

Ian Heath Gershengorn
Jenner & Block

Michele Johnson
Tennessee Justice Center

Arian M. June
Debevoise & Plimpton LLP

Jane Preyer
Environmental Defense Fund (Ret.)

Lourdes A. Rivera
Pregnancy Justice

Donald B. Verrilli, Jr.
Munger, Tolles & Olson

Stephen Williams
Houston Health Department

Ronald L. Wisor, Jr.
Hogan Lovells

Senior Advisor to the Board
Rep. Henry A. Waxman
Waxman Strategies

General Counsel
Marc Fleischaker
Arent Fox, LLP

January 8, 2024

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-AV22; CMS-9895-P
Patient Protection and Affordable Care Act,
HHS Notice of Benefit and Payment
Parameters for 2025; Updating Section 1332
Waiver Public Notice Procedures; Medicaid;
Consumer Operated and Oriented Plan (CO-
OP) Program; and Basic Health Program**

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 2025; Updating*

Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program (hereinafter NBPP 2025 Rule).

PART 435 – ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

§ 435.601 – Application of financial eligibility methodologies

We do not support HHS’s proposal to increase states’ flexibility in using the income and resource disregards that are authorized by Social Security Act § 1902(r)(2) for discrete cohorts of individuals within Medicaid eligibility groups. This is a significant reversal of policy with potential for major consequences, yet HHS has made this change with little explanation, in a rule primarily focused on the Marketplaces. HHS largely fails to acknowledge, much less engage with, the possible impact of this provision.

Since 1993, § 435.601(d)(4) has required that less restrictive methodologies be comparable for everyone in an eligibility group. HHS’s 2001 guidance confirmed this requirement.¹ As recently as 2021, HHS interpreted §§ 1902(r)(2) and 1902(a)(17) to require comparability in application of methodologies.² In the preamble to the proposed rule, however, HHS provides minimal justification for reversing this longstanding policy and shows no evidence that it fully considered its potential consequences. This lacks transparency and risks running afoul of the Administrative Procedures Act.

Nor do we support this policy. While it has the potential to expand coverage, it does so in a way that enables states to create a patchwork of eligibility rules that would be difficult for applicants (and the constantly rotating roster of eligibility workers) to understand and result in coverage of some people while similarly situated people in the same eligibility group are left out. It also, as HHS acknowledges, creates the risk that states could also use the authority to “narrow an existing disregard that is [currently] broadly available to an eligibility group to discrete members of the group.”³ To guard against potential cutbacks in eligibility, HHS proposes only to require states to submit a state plan amendment that is “reasonable” and “does not violate other Federal statutes.” But, because HHS does not specify how it would evaluate reasonableness or how it

¹ CMS, Medicaid Eligibility Groups and Less Restrictive Methods of Determining Countable Income and Resources: Questions and Answers (May 11, 2001), <https://www.ezelderlaw.com/wp-content/uploads/gamedicaid/CMS/elig0501.pdf>.

² CMS, Dear State Medicaid Director Letter at 3 (SMD #21-004) (Dec. 7, 2021), https://www.medicaid.gov/sites/default/files/2021-12/smd21004_0.pdf.

³ 88 Fed. Reg. 82,525.

would determine whether a proposal complied with statutes such as Title VI or the ADA, this would provide little protection to Medicaid applicants or beneficiaries.

This change in policy raises many questions. To raise a few – does this policy create the risk that more powerful interests, such as nursing facilities, will successfully press for applications of less restrictive methodologies that favor individuals who need nursing facility services over those who need HCBS? Might states target individuals in certain lines of work with income disregards, based on pressure from certain industries? Might states target politically disfavored groups, e.g. the not-working poor?

Moreover, we do not agree that neither § 1902(a)(17) nor § 1902(a)(10)(B) require comparability among individuals in an eligibility group. In fact, only two years ago, HHS took the position that § 1902(a)(17) required that less restrictive methodologies be comparable for all individuals in an eligibility group.⁴ Moreover, recent legislation suggests that Congress believes that § 1902(a)(17) would prevent application of less restrictive methodologies in the manner HHS is proposing here. In the Sustained Excellence in Medicaid Act, Congress authorized states to target less restrictive methodologies to those who need certain HCBS. To do so, the legislation specifically exempts such targeting from § 1902(a)(17).⁵ Finally, we are concerned that such a significant change in agency policy without confirming congressional authorization, the Major Questions Doctrine could well be triggered.

We urge HHS to withdraw this proposed change and, if it decides to go forward with it in the future, re-issue it in a separate rule with more detailed explanation of how this policy is consistent with the Medicaid Act and with guardrails that require less restrictive methodologies targeting persons within an eligibility group be carefully targeted, based on a sound rationale, and that do not discriminate based on race, national origin, language, sex, gender identity, sexual orientation, disability, age or health condition.

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

§ 155.170 – Additional Required Benefits

HHS proposes to amend the Essential Health Benefits (EHB) regulations to clarify that a covered benefit that is part of a state’s EHB benchmark will be considered an EHB and

⁴ CMS, Dear State Medicaid Director Letter at 3, *supra* note 2 (SMD #21-004)

⁵ See Sustaining Excellence in Medicaid Act, Pub. L. No. 116-39, § 1 (2019).



therefore not subject to defrayal, regardless of the benefit's status as a benefit mandated through state action. NHeLP welcomes this proposed change as we believe it will further incentivize states to seek modifications and improvements to their benchmark plans by addressing concerns about defrayal without running afoul of the ACA's requirements regarding benefits in addition to EHB. Despite our strong support for the proposal, however, we are disappointed to see that HHS is not clarifying lingering questions about the defrayal process given the impact the policy is having on states' ability to address unmet health needs outside of the benchmarking process.

A. The proposed amendment would further incentivize states to seek changes to the EHB benchmark as a vehicle to address unmet health needs.

The ACA allows states to require coverage of benefits in addition to EHB as long as they defray the cost of providing such services.⁶ Throughout the years, HHS has implemented the defrayal provision by specifying that mandates in addition to EHBs are those that are enacted through state action after December 31, 2011 unless those mandates are necessary for compliance with federal requirements.⁷ This language has proven difficult to navigate under the current EHB benchmarking rules, which essentially allow states to adopt any new coverage mandate as long as the resulting benchmark plan does not exceed the actuarial limit.

In response to this apparent conundrum, HHS clarified that states would not have to defray the cost of new coverage mandates adopted through the EHB benchmarking process.⁸ This policy has been key in moving states to use the new benchmarking opportunities as a tool to address unmet health needs by adding coverage mandates through benchmarking. Under this policy, states have added coverage requirements for hearing aids, services for substance use disorders (SUD), gender-affirming care services, and other services that particularly benefit underserved communities.

HHS's policy, however, left open the possibility that states would be subject to defrayal for services that are mandated through a post-2011 state action regardless of the presence of the services in the EHB benchmark plan. Thus, for example, a state that wishes to extend a coverage mandate already contemplated in the EHB benchmark to plans not subject to EHB requirements would have to adopt a mandate through state

⁶ 42 U.S.C. § 18031(d)(3)(B)(i).

⁷ 45 C.F.R. § 155.170(a)(2).

⁸ CMS, *Frequently Asked Questions on Defrayal of State Additional Required Benefits*, Oct. 23, 2018, <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faq-defrayal-state-benefits.pdf>.



action that is carefully crafted to apply solely to non-EHB plans. If the adopted mandate is broad, it will likely result in the state having to defray the cost for Qualified Health Plans (QHPs) of a mandate that was already in place through the benchmark plan. Therefore, because of the current policy, states run the risk of inadvertently running into defrayal problems for benefits that were already covered by QHPs. Not only does this result make little sense, but it also does not comport with the language of the ACA and does not promote a particular goal of HHS.

Similarly, the current policy serves as a barrier for states that are seeking to adopt new coverage mandates concurrently via state action and benchmarking. Changes to the EHB benchmark plan take a long time. A state that identifies a particular need in the summer of 2024, for example, would not be able to adopt the new coverage mandate until, at a minimum, plan year 2027. States may legitimately believe that the EHB timeline is unacceptable when lack of coverage for a particular service is contributing to health disparities and worsening the health of the state's population. As a result, some states have contemplated the option of enacting a mandate through legislation or administrative action that has immediate effect, while at the same time pursuing changes to the EHB benchmark for a later date.

While these states will likely be subject to defrayal for the period of time that a state mandate exists without the equivalent mandate on the benchmark side, states may be willing to assume the costs of the services temporarily in order for the benefits to take effect sooner, as long as they have the assurance that they will cease to defray the costs once the benchmark requirement takes effect. HHS's current policy, however, seems to indicate that once a state is subject to defrayal, it will continue to have to defray even if a benchmark change is subsequently adopted. This seems to be an unintended loophole in the current rules that is not necessary to advance the goals of the ACA and its only effect is to deter states from seeking necessary coverage changes. We therefore strongly support HHS's proposal to remove the threat of defrayal when the benefit requirement is adopted via the benchmarking process.

B. HHS should use the NBPP to clarify the process for states to avoid defrayal when enacting coverage mandates for compliance with federal requirements.

In recent years, NHeLP has provided extensive technical assistance to state advocates and policymakers who are seeking to address health disparities and unmet health needs through legislation and other state action and who are confronted with the reality that they may have to defray the cost imposed on plans for covering such new benefits. Some states have desisted from pursuing necessary action to close gaps in access to



health care services altogether. Others have instead moved on to pursuing EHB benchmark changes despite the fact that such a move requires delaying availability of essential services. This reality is in line with the ACA's vision that states may not add new coverage mandates outside of the EHB process unless they defrayed the costs of such services.

However, as HHS appropriately identified in the defrayal rule, the ACA could not have intended for states to defray the cost of a new mandate that is enacted only for the purpose of enforcing or ensuring compliance with a particular federal requirement. In essence, such mandates are not *new* mandates because the federal rule they seek to enforce already requires coverage of a certain benefit. In addition, cost considerations are inapplicable when a state mandate only seeks to enforce federal rights. Rights are rights no matter the financial implications of their enforcement. Therefore, it is appropriate for HHS to exempt from defrayal specific mandates that are based on federal requirements already in place.

Despite the importance of this exception, it remains vastly underutilized in part because confusion persists about the meaning of the rule. For instance, states are unaware about the process for using the exception. Because states are ultimately responsible for identifying new mandates subject to defrayal, some states have enacted mandates under the justification that the lack of coverage for a specific service contravenes federal non-discrimination or behavioral health parity rules without waiting for HHS approval or consulting with the agency during the enacting process. Others have foregone a finding that a state mandate is necessary for compliance with federal rules based on the concern that HHS may subsequently overrule the state's finding and require the state to defray the cost of the new service in the future.

The inconsistent way in which states have pursued or failed to pursue coverage requirements based on the exception to defrayal underscores the need for HHS to clarify the language and provide examples of situations in which the exception applies. Moreover, we believe HHS should use this opportunity to formalize or clarify the process for states to take advantage of the exception. While stakeholders have repeatedly heard that CCIIO staffers are available for technical assistance, we believe the ad hoc nature of the current process is a disincentive for states that are considering solutions to persisting health needs among their populations.

To clarify the defrayal exception, we urge HHS to explicitly address the policy in the preamble to the final rule. The preamble should discuss specific instances that would trigger the exception and highlight examples from states that have successfully utilized



the exception. For example, HHS could cite Washington’s statute requiring coverage of behavioral health crisis services and the subsequent memo from the Office of the Insurance Commissioner explaining that such mandate was necessary to ensure compliance with the federal Mental Health Parity and Addiction Equity Act (MHPAEA).⁹ Similarly, HHS could cite Colorado’s action to enact a coverage mandate for infertility treatment and the corresponding letter from the Colorado Division of Insurance explaining that the mandate ensures plans are in compliance with federal nondiscrimination requirements.¹⁰ HHS should generally emphasize states’ ability to enforce nondiscrimination requirements (including EHB nondiscrimination requirements and requirements of § 1557 of the ACA) and behavioral health parity requirements, while reiterating that states may use the exception to enforce or ensure compliance with any federal requirement regarding health care coverage, as long as the state properly documents its reasoning.

Moreover, HHS should clarify that a state may take advantage of the exception without the existence of a court order or opinion questioning plans’ compliance with a specific federal requirement based on the selected benchmark plan in the state. The existence of a court order can serve as support for a state’s contention that a mandate enacted through state action is needed to ensure compliance with federal requirements, but we urge HHS to avoid making the existence of a court order a necessary precondition for states to use the exception to defrayal. States are important players in ensuring compliance with federal law. In fact, states are the main enforcers of federal parity requirements and the documented lack of enforcement responds to uneven enforcement actions across the different states. Similarly, given the role that states play in defining EHBs through the benchmarking process, states have become important enforcers of the requirement that EHB benefit designs do not discriminate based on age, disability, or expected length of life. The significant role states play in ensuring compliance and enforcing federal law underscores the importance of giving states considerable discretion in using the exception to defrayal.

We also urge HHS to outline a process for states to take advantage of the defrayal exception. The preamble to the 2025 NBPP should state that CCIIO staffers are

⁹ Wash. Off. of the Ins. Comm’r, *Memorandum Re: Behavioral Health Emergency Services Under E2SHB 1688* (Chap. 263, Laws of 2022) (May 6, 2022), <https://www.insurance.wa.gov/sites/default/files/documents/e2shb-1688-mhpaea-memo.pdf>.

¹⁰ Colo. Div. of Ins., *Letter to CCIIO Re: Colorado Analysis of Essential Health benefits and Infertility Coverage* (July 30, 2020), <https://drive.google.com/file/d/1SE0oOBERejVfi8GN6F8JPqjzZY9JN06g/view>.



available to consult with state agencies, legislators, and other policymakers who are interested in adopting a mandate through state action outside of the benchmarking process. The process should also envision consultation with other departments within HHS as well as other federal agencies, as needed to analyze and respond to the legal rationale behind the state's decision to pursue a mandate to ensure compliance with federal requirements. The process could also include a requirement for states to submit a letter to CCIIO formally announcing the adoption of the mandate and explaining the state's rationale that the mandate is not subject to defrayal because it is needed for compliance with federal requirements. Finally, HHS should clearly indicate in the preamble whether it intends to reserve the right to overrule a state's decision and therefore trigger defrayal after the adoption of a state mandate.

In summary, we recommend that HHS:

- provide examples of instances or situation that may trigger the exception to defrayal, including examples from states that have successfully used it;
- clarify that states may use the exception without a court order; and
- outline a process for states to consult with HHS about the defrayal exception.

§ 155.205 Consumer assistance tools and programs of an Exchange

As we have seen throughout the unwinding of Medicaid's continuous coverage requirements, Call Centers are an essential component of providing consumer assistance and ensuring consumers can apply for and maintain coverage. Without an effective Call Center, many individuals may not get their questions answered, may not understand what to do when they receive a confusing notice, may not know what documents or additional information they need to provide, may not know how to resolve data inconsistencies, and may lose coverage despite remaining eligible. Call center delays prevent individuals from receiving timely information and coverage. Many Medicaid Call Centers have had staggeringly long wait times for individuals, resulting in many individuals hanging up as they can no longer wait.¹¹

These issues are compounded for individuals with limited English proficiency (LEP) and individuals with disabilities. For example, a report from UnidosUS found that Spanish-language callers calling Florida's Medicaid call center had to wait nearly four times as

¹¹ Michelle Yiu and Elizabeth Edwards, *Unwinding Call Center Data Shows Ongoing Problems*, Nat'l Health Law Prog. (2023), <https://healthlaw.org/resource/unwinding-call-center-data-shows-ongoing-problems/>.

long as an English-language caller.¹² NHeLP has developed a list of questions to help ascertain whether Call Centers are effectively serving LEP and people with disabilities.¹³ We suggest that many of these questions should be utilized by CCIIO to determine if a state's Exchange is operating an effective call center.

Given the problems we've seen during unwinding as well as the likely challenges CCIIO would have at ensuring an effective Call Center without actual standards, we strongly recommend that CCIIO establish specific standards for Call Centers to ensure that they provide effective and timely assistance in general and further ensure that the same standards apply for LEP and people with disabilities. We further encourage that rulemaking establish specific minimum standards for call center wait times and abandonment rates to ensure individuals have reasonable access to the supports this rule seeks to improve.

§ 155.302 – Options for Conducting eligibility determinations

We support the proposal to require SBMs to operate a centralized eligibility and enrollment platform, allowing for the submission of the single, streamlined application for enrollment in a QHP and insurance affordability programs by consumers through the SBM website. We additionally support the clarification that the state marketplace, other state agencies, and eligible state contractors are solely responsible for determining eligibility for QHPs and insurance affordability programs. We agree that applicants and enrollees could be harmed if an entity other than the exchange conducted eligibility determinations, for instance because they may receive inconsistent, confusing, or inaccurate results and information that could impact their receipt of financial assistance, their plan choice, or their tax liability.

§ 155.305 – Eligibility Standards

We appreciate that HHS acknowledges that notice is important to ensuring that individuals understand their obligations to keep their APTCs and why they may be

¹² UnidosUS, *At Florida's Medicaid call center, long and discriminatory delays prevent eligible families from keeping their health care*, <https://unidosus.org/publications/long-and-discriminatory-delays-at-floridas-call-center/>.

¹³ Elizabeth Edwards and Mara Youdelman, *Medicaid Eligibility Call Centers: Questions for LEP & Disability Access*, Nat'l Health Law Prog. (2023), <https://healthlaw.org/resource/medicaid-eligibility-call-centers-questions-for-lep-disability-access/>.

terminated.¹⁴ And we support the change to § 155.305(f)(4) that requires an initial notice to tax filers who may be at risk of ineligibility for APTCs if they fail to file and reconcile (FTR) for a second consecutive year. However, as NHeLP has stated repeatedly in letters and comments to HHS, the FTR process continues to be plagued with due process problems that need to be addressed.¹⁵ In particular, the information provided in the various FTR notices, which should include a clear explanation of what the FTR requirement is and consequences to coverage, does not meet due process standards and the decision-making process for FTR is not reliable.¹⁶ Although we generally support the proposed rule changes regarding FTR, we again request that HHS fix the deficiencies in the FTR process. In addition, HHS should neither deny nor terminate APTCs due to FTR until those issues are addressed and fully tested.¹⁷ This includes not starting the two-year process until it can be assured that the notice process is adequate and the FTR processes are well tested.

¹⁴ 88 Fed. Reg. 82,572.

¹⁵ Nat'l Health Law Prog., *Comments on the HHS Notice of Benefit and Payment Parameters for 2024 Proposed Rule 6-8* (Jan. 30, 2023), <https://healthlaw.org/resource/nhelp-comments-on-patient-protection-and-affordable-care-act/>; Nat'l Health Law Prog., *Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 15-17* (Nov. 27, 2017), <https://healthlaw.org/resource/nhelp-comments-on-hhs-2019-proposed-rule-change-to-benefit-payment-parameters/> (describing the due process violations with the FTR notices and processes); see also NHeLP Letters to CCIIO regarding the FTR process on Aug. 24, 2017 and Oct. 19, 2017 (on file) [hereinafter "NHeLP FTR Comments"]. Based on the information in the preamble, NHeLP is assuming for these comments that the FTR notices have not changed significantly since we last reviewed and commented on them.

¹⁶ *Id.* In NHeLP's comments on the 2024 NBPP Proposed Rule we discussed in detail the problems with the reliability and timeliness of the IRS data. We do not repeat those again here, but incorporate those concerns by reference to our comments as those concerns remain the same as the Preamble to the 2025 NBPP Proposed Rule do not indicate improvements in this area.

¹⁷ U.S. Const. Amend. XIV; *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 14 (1978); *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314-15 (1950) (requiring "notice reasonably calculated, under all circumstances, to apprise intended parties of the pendency of the action and afford them an opportunity to present their objections" and that "[t]he means [of notice] employed must be such as one desirous of actually informing the absentee might reasonably adopt to accomplish it."); *Goldberg*, 397 at 267-68 (requiring "timely" notice "detailing the reasons for a proposed action"); *Mathews v. Eldridge*, 424 U.S. 319, 348 (1976) (risk of erroneous deprivation through procedures being used); *Carey v. Quern*, 588 F.2d 230, 232 (7th Cir. 1978) (due process requires the assistance program be administered to insure fairness and avoid risk of arbitrary decision making).

The notices sent under proposed § 155.305(f)(4) would contain different information based on whether the household contact is the tax filer or not. As NHeLP has commented before, while we recognize the challenges in sending protected Federal tax information (FTI), APTC recipients cannot be sent notices that do not meet constitutional requirements.¹⁸

For the tax filers, the proposed § 155.305(f)(4) would allow the FTR Open Enrollment notices sent directly to the tax filer to state that the IRS data indicates the tax filer failed to file and reconcile. The notices to anyone affected by the FTR must provide minimally sufficient information, including financial calculation and household filing information, for their APTCs being at risk due to the FTR and what they must do to keep their APTCs.¹⁹ That the FTR process requires two year of noncompliance means that the person must be able to fully understand the process, the requirements, and when and how they will be able to dispute the findings of noncompliance.

The permission in the 2025 NBPP Proposed Rule to send non-tax filers “broad, general language regarding FTR” that would potential include multiple reasons why a person is at risk of APTC discontinuation is constitutionally insufficient.²⁰ As noted in previous NHeLP comments, including multiple potential reasons for why an individual may be losing APTCs does not provide the individual with the legal and factual bases for the decision or the individualized reasons.²¹ While the preamble discusses that the notices

¹⁸ See *supra* note 2 (citing *Comments on the HHS Notice of Benefit and Payment Parameters for 2024 Proposed Rule* 6-8).

¹⁹ While the OE 2021 FTR Warning Notice to tax filers includes more direct information than previous notices about the FTR process and taking remediating actions if the person has not filed, and how to appeal if the Marketplace ends coverage, it is not clear that the final FTR notices will contain the specific information needed to meet due process requirements. CMS, Failure to Reconcile Open Enrollment Warning Notices (Nov. 2020), <https://www.cms.gov/marketplace/applications-and-forms/ptr-open-enrollment-warning-notice.pdf>. In addition, the Failure to Reconcile Recheck Warning Notices do not indicate what the final notices will look like and whether they will meet due process requirements. CMS, Failure to Reconcile Recheck Warning Notices (July 2020), <https://www.cms.gov/marketplace/in-person-assisters/applications-forms-notices/notices>.

²⁰ 88 Fed. Reg. 82571.

²¹ Nat'l Health Law Prog., *2024 NBPP Proposed Rule Comments*, *supra* note 2, at 7; see, e.g., *Goldberg v. Kelly*, 397 U.S. 254, 267-68 (1970) (requiring detailed reasons in notice, including “the legal and factual bases”); *Gray Panthers v. Schweiker*, 652 F.2d 146, 168 (D.C. Cir. 1981) (without adequate notice of reasons for denial “hearing serves no purpose.”); *Barry v. Lyon*, 834 F.3d 706, 720 (6th Cir. 2016) (agency must provide

discussed in the proposed § 155.304(f)(4) would create opportunities for education on the requirement and take action, such notices will only do so if they provide sufficient information to provide understanding and prompt action.²² While we recognize there may be issues with FTI, the notices to the non-tax filers must contain sufficient information so that they may take action to protect their benefits. A bare minimum of information about the reason behind why the APTC noncompliance must be provided. If that information cannot be provided, the FTR process must not start until HHS can address those barriers.

We also agree that significantly more outreach is needed not only to beneficiaries, but to tax preparers, about the FTR process and the risk of noncompliance. We appreciate that the 2024 NBPP Proposed Rule acknowledges this need, but are concerned that it does not set expectations for additional outreach other than these proposed notices.²³ Given the complexity of this issue and that people are unfamiliar with the expectation and process, additional outreach activities should be described so that Exchanges are clear on the expectation outside of the proposed notice. Understandable and accurate information about the process for determining eligibility is critical.²⁴ The dangers of losing coverage are well documented, as are the impacts of losing APTC coverage and the high risk of not re-enrolling.²⁵

While we support that affected individuals will receive notice, we ask that the FTR process not be restarted until HHS can provide a fully constitutionally sufficient FTR process, including notices for everyone affected. In addition, we reiterate our long-running ask that before FTR is ready to relaunch, HHS must test the data exchanges and decision-making processes to ensure that erroneous decisions are not being made

“specific, individualized reasons for the agency action”); *Rodriguez v. Chen*, 985 F. Supp. 1189, 1195 (D. Ariz. 1996) (public interest in assuring health benefits will not be erroneously terminated or denied outweighs inconvenience to the state and the notice must include specific financial information where applicable so that errors may be corrected); *Ortiz v. Eichler*, 616 F. Supp. 1046, 1062 (D. Del. 1985), aff’d 794 F.2d 880 (3d Cir. 1986) (requiring notice include what financial information was considered and relevant calculations if calculations of income are involved in the eligibility decision).

²² 88 Fed. Reg. 82572.

²³ *Id.*

²⁴ See, e.g., *Goldberg*, 397 U.S. at 267-68; *Goss v. Lopez*, 419 U.S. 565, 579 (1975) (due process has little reality or worth unless a person understands the issue is pending); see also *Waldrop v. New Mexico Dept. Hum. Servs. Dep’t*, No. CV 14-047 JH/KBM, 2015 WL 13665460, at *24 (D.N.M. Mar. 10, 2015) (beneficiary must be provided notice about the process).

²⁵ 87 Fed Reg. 78256-57.



and that the data is accurate, timely, and otherwise reliable.²⁶ In addition, the notices used throughout the process must properly inform beneficiaries of the process, requirements, bases of any decisions (including any relevant financial or household filing data), and process for requesting an appeal. While we recognize that there is also a need to avoid individuals from accumulating significant tax liability, we believe interim processes can be implemented to notify people of the FTR requirement, processes, and consequences.

§ 155.315 – Verification process related to eligibility for enrollment in a QHP through the Exchange

We support the proposal to revise § 155.315(e) to allow Marketplaces to accept incarceration attestations without further verification. As HHS notes, this flexibility could result in significant cost savings. Current procedures require Marketplaces to check a third-party database to determine incarceration status. Under the current process, if an applicant attests they are not incarcerated, the discrepancy must be resolved through a data matching issue (DMI). DMIs are both time consuming and burdensome, and require applicants to submit additional documentation to prove they are not incarcerated. The current procedures have resulted in high numbers of DMIs, but as HHS demonstrates the vast majority of these has been resolved in favor of the applicant.²⁷ As HHS states, the DMI process has also negatively affected consumer experience. In particular, we agree with HHS, that the DMI process creates unique burdens for formerly incarcerated individuals, a population that includes a large number of people with disabilities. We also agree with HHS’s assertion that the current system may exacerbate racial inequities, given for example, that Black individuals are incarcerated at 5 times the rate of white individuals.²⁸ Given all of this, we support the proposed revision, and believe that it will help lead to cost savings and better access to health coverage and health care for consumers.

²⁶ See *supra* note 2 (citing *Comments on the HHS Notice of Benefit and Payment Parameters for 2024 Proposed Rule 6-8*).

²⁷ Proposed Rule, 88 Fed. Reg. 82573 (noting that in one study 96.5% of DMIs were resolved in favor of the applicant).

²⁸ See also, Sabrina Corlette & Jason Levitas, *Proposed 2025 Payment Rule: Marketplace Standards And Insurance Reforms*, HEALTH AFF. FOREFRONT (2023), <https://www.healthaffairs.org/content/forefront/proposed-2025-payment-rule-marketplace-standards-and-insurance-reforms> (noting that the current system “aggravates racial inequities”).

§ 155.330 – Eligibility redeterminations during a calendar year

We support the proposed changes to proposed § 155.330, which would allow the Secretary to suspend periodic data matching (PDM) between Medicaid, CHIP, Medicare, and Basic Health Programs (BHP) and the Marketplace during exigent circumstances when data becomes unavailable or unusable. We agree that the authority under ACA §§ 1411 and 1413 gives the Secretary the authority to establish appropriate procedures to ensure eligibility determinations are accurate, particularly to protect access for individuals who are eligible for insurance affordability programs.

PDM between Medicare, Medicaid, BHP, or CHIP and the Marketplace frequently result in erroneously termination of coverage during times of normal operation.²⁹ Lack of accurate program enrollment data, eligibility miscalculations, administrative barriers, and system glitches lead to individuals being inappropriately disqualified from these programs and contribute to high rates of churn, particularly for low income and underserved communities.³⁰ However, the converse is also true: states that conduct fewer PDMs have lower rates of disenrollment and churn between and out of programs during times of normal operation.³¹

The PHE Unwinding exacerbated these problems. For PDM to work as intended, state enrollment data must be accurate and up-to-date; however, the economic downturn following the onset of the COVID-19 pandemic and the resulting surge in enrollment burdened state public health systems and insurance affordability programs and compromised the reliability of enrollment data.³² To preserve health care access during

²⁹ Gov't Accountability Ofc., *Medicaid: Data Completeness and Accuracy Have Improved, Though Not All Standards Have Been Met* (Jan. 14, 2021), <https://www.gao.gov/assets/720/711841.pdf>; Bradley Corallo et al., KFF, *Medicaid Enrollment Churn and Implications for Continuous Coverage Policies*, Dec. 14, 2021, <https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-churn-and-implications-for-continuous-coverage-policies/>.

³⁰ Suzanne Wikle et al., Ctr. Pol'y & Budget Priorities & CLASP, *States Can Reduce Medicaid's Administrative Burdens to Advance Health & Racial Equity* (2022), <https://www.cbpp.org/research/health/states-can-reduce-medicaids-administrative-burdens-to-advance-health-and-racial>.

³¹ Medicaid & CHIP Payment & Access Comm'n (MACPAC), *An Updated Look at Rates of Churn and Continuous Coverage in Medicaid and CHIP* (2021), <https://www.macpac.gov/wp-content/uploads/2021/10/An-Updated-Look-at-Rates-of-Churn-and-Continuous-Coverage-in-Medicaid-and-CHIP.pdf>.

³² State Health & Value Strategies, *Tracking Medicaid Coverage Post the Continuous Coverage Requirement: Using Data Dashboards to Monitor Trends 2* (Jan. 2022),

this critical time, states needed to take reasonable steps to maximize health care coverage, including pausing PDM. Currently, during the PHE Unwinding, accurate Medicaid enrollment data is critical to ensure that consumers seeking coverage can successfully transition to the Marketplace. States that rely on outdated or inaccurate enrollment data may prevent individuals from obtaining coverage due to barriers created by PDM.

We strongly recommend HHS adopt more specific language that defines what “certain situations or circumstances” result in poor data availability such that PDM should be suspended.³³ For example, certain states experience perpetual data quality challenges, resulting in lingering Medicaid and CHIP eligibility and enrollment data quality issues.³⁴ National emergencies, such as the COVID-19 pandemic, result in fluctuating enrollment and high need that should certainly trigger PDM pauses. However, there are many circumstances beyond a public health emergency during which compromised data quality and accuracy leads to lapses in coverage for eligible individuals. HHS should clarify that PDM should be paused when poor enrollment data is likely to lead to individuals incorrectly losing coverage. We encourage HHS to provide examples in guidance that illustrate scenarios when PDM should be paused.

§ 155.335 Annual Eligibility Determinations

There has long been a renewal and re-enrollment hierarchy described at 45 C.F.R. § 155.335(j) that allows consumers with metal-level QHPs to be automatically reenrolled into the same or a comparable metal plan if they do not actively select a different QHP. The proposed amendment would incorporate consumers with a catastrophic plan into the auto re-enrollment hierarchy rules. Specifically proposed changes to § 155.335(j)(1) and (2) would “require Exchanges to re-enroll individuals who are enrolled in catastrophic coverage...into a new QHP for the coming plan year.”³⁵

We recognize that there needs to be a default process for auto-renewing people who do not actively return to the Exchange to make plan choices during open enrollment. However, auto reenrollment does not address the critical need to develop effective ways

https://www.shvs.org/wp-content/uploads/2022/01/Tracking-Medicaid-Coverage-Post-the-Continuous-Coverage-Requirement_Using-Data-Dashboards-to-Monitor-Trends.pdf
(noting significant lag in states reporting enrollment data to CMS).

³³ 88 Fed. Reg. 82578.

³⁴ See Gov’t Accountability Ofc., *supra* note 29.

³⁵ <https://www.govinfo.gov/content/pkg/FR-2022-12-21/pdf/2022-27206.pdf>.



to encourage consumers to play an active role in evaluating their plan choices each year.

We support the proposed changes to § 155.335 that would add to the automatic re-enrollment hierarchy individuals who are enrolled in catastrophic coverage so that they will also maintain coverage even when they fail to respond. We also support the protection added in § 155.335(j)(5) that would prohibit individuals enrolled in metal-level coverage from being newly auto re-enrolled into catastrophic coverage. An individual should only be automatically re-enrolled into a plan that provides at least equivalent if not better coverage.

§ 155.400 – Enrollment of qualified individuals into QHPs

We support the proposed amendment to proposed § 155.400(e)(2) to clarify that the Federally Facilitated Marketplaces (FFMs) will, and State Based Marketplaces (SBMs) will have the option of, allowing issuers the option of extending premium payments in certain circumstances. As this section explains, in the 2018 payment rule, HHS recognized that during Open Enrollment Periods (OEPs), issuers often experienced technical difficulties and processing errors in processing binder payments (the first premium payment required to enroll in a health plan). Given this, HHS amended § 155.400(e)(1) to codify that FFMs will, and SBMs have the option of, extending deadlines for binder payments to ensure that enrollees do not experience disruptions in enrollment or coverage. The current amendment would clarify that this flexibility applies not only to binder payments, but to all premium payments.

§ 155.410 – Initial and annual open enrollment periods

We support the proposed revision to proposed § 155.410(e)(2) that would require SBMs not utilizing the federal platform to adopt an open enrollment period that begins on November 1 and runs through at least January 15, with the option to extend the open enrollment beyond January 15. We agree with HHS that this proposal will benefit consumers by providing ample time to consider plan options, to connect with Navigators and assisters who can help support consumers through the process, and to analyze updated cost-plan information that may not become available until January.³⁶ We also

³⁶ In 2021, NHeLP supported HHS's proposal to extend OEPs in the Federally Facilitated Marketplaces, but we suggested that open enrollment be extended through January 31. We are glad to see that HHS will allow states to consider an OEP that extends past January 15 here. We also encourage HHS to revisit the open enrollment for FFMs in future rulemakings and to consider extending the date. See Wayne Turner

agree that revising this section will help protect against the possibility of shortened enrollment periods in future years.

§ 155.420 Special Enrollment Periods

We support the proposal to allow people who select and enroll in coverage through an SEP with a regular coverage effective date to receive coverage on the first day of the month after plan selection.

We strongly support the proposal to decouple the low-income SEP from the zero percent required premium contribution. Additionally, we urge CMS to extend the low-income SEP to people with an annual household income of up to 250% FPL and to require SBMs to adopt this SEP. By increasing the income threshold for this SEP to 250% FPL, an additional 4.3 million uninsured people would become eligible to enroll under an expanded year-round SEP. This group includes approximately 4 million adults aged 18-64 and over 300,000 children. Groups that face barriers to coverage, including people of color and self-employed individuals, are overrepresented in the population that would become eligible for an expanded SEP.³⁷

The proposed rule also notes that, even if people with incomes at or below 150% FPL were not eligible for \$0 premium silver plans, they would still likely remain eligible for \$0 bronze plans, reducing the likelihood that more expansive enrollment opportunities would lead them to wait until they are sick to enroll in coverage. Similarly, minimal premiums are available to people with incomes in the 150-250% FPL range. In 2023, the average net premium for the lowest cost silver plan available to a family of four

et al., NHeLP Comments on Updating Payment Parameters Rule (July 28, 2021), <https://healthlaw.org/resource/nhelp-comments-on-updating-payment-parameters-rule/>.

³⁷ CBPP analysis of 2022 American Community Survey data. Eligibility estimated based on modified adjusted gross income, immigration status, age, self-identification as American Indian or Alaska Native, and state of residence. People who are eligible for Medicaid or CHIP are not included. Estimates also do not include people who are already eligible for a year-round SEP under their state policies or under special provisions for American Indians and Alaska Natives.



earning 250% FPL was just \$1.³⁸ And many people in this somewhat higher income bracket are already eligible for a \$0 net premium silver or gold plan.³⁹

§ 155.430 Termination of Exchange Enrollment or Coverage

We support the proposal to allow Exchange enrollees who enroll in Medicare Part A or B retroactively to terminate marketplace enrollment retroactively (no earlier than the first day of retroactive Medicare enrollment). We support CMS' position that it is important to allow people who do not have the ability to cancel Exchange coverage prospectively, because they have been enrolled in Medicare retroactively, the opportunity to avoid having overlapping coverage.

This will save money for the federal government, which would receive APTC back for up to two months of marketplace coverage, and for individuals, who would receive a refund for their share of premiums for up to two months of marketplace coverage. This could be particularly important for the groups of enrollees more likely to receive retroactive Medicare eligibility, including:

- People with disabilities who are finishing the 24-month waiting period for Social Security Disability Insurance (SSDI) benefits, who may be experiencing significant financial strain because of the effect their disability may have on their income and expenses;
- People who must pay a premium for Medicare Part A (who are not automatically enrolled), who do not qualify for Social Security benefits and may include some people who are immigrants; and
- People who are formerly incarcerated, who may have enrolled in marketplace coverage upon release but who eventually opt to receive retroactive Medicare coverage.

We support this being optional for marketplace enrollees, as it may be confusing for some enrollees to notify providers and ensure that claims sent to (or paid by) a QHP issuer are rerouted to Medicare.

³⁸ CCIIO, "Plan Year 2023 Qualified Health Plan Choice and Premiums in HealthCare.gov Marketplaces," October 26, 2022, <https://www.cms.gov/cciio/resources/data-resources/downloads/2023qhppremiumschoicereport.pdf>.

³⁹ Jared Ortaliza et al., "Millions of Uninsured People Can Get Free ACA Plans," KFF, January 10, 2023, <https://www.kff.org/policy-watch/millions-of-uninsured-people-can-get-free-aca-plans/>.



We also recommend that individuals who receive retroactive Medicaid coverage should also have the option to terminate marketplace coverage retroactively. Retroactive Medicaid coverage could occur for a number of reasons including:

- Reinstatement after a procedural termination during the unwinding of Medicaid's continuous coverage provision after the individual was transferred to the marketplace and enrolled in coverage;
- Reinstatement after CMS working with a state to correct unlawful terminations during the unwinding of Medicaid's continuous coverage provision after the individual was transferred to the marketplace and enrolled in coverage;
- Delays in processing of enrollment, particularly in a state that provides 3 months retroactive Medicaid coverage from the date of enrollment if the individual maintained marketplace coverage while awaiting a Medicaid decision; and
- Reinstatement after litigation challenging an individual's denial of eligibility or termination.

Given that by definition Medicaid enrollees have very low incomes, the ability to request retroactive termination and refund of any paid premiums, co-pays and co-insurance could greatly support the financial health of affected individuals.

§ 155.1050 – Establishment of Exchange Network Adequacy Standards

We support HHS's proposal to require State Exchanges and State-based Exchanges to meet the same qualitative network adequacy standards as the Federally Facilitated Exchange. NHeLP has long encouraged HHS to set a national floor for network adequacy in all Exchanges to ensure that QHPs in State Exchanges and SBE-FPs are subject to at least the same standards that are applied to their counterparts in the FFE. We commend HHS for proposing to amend the regulation to set such a floor across all Exchanges that will balance the need for a national standard and state flexibility by allowing states to perform their own reviews of network adequacy while ensuring that the standards and review process are at least as stringent as the established federal standards and process. Moreover, we believe that giving State Exchanges and SBE-FPs until 2025 to come into compliance with these requirements provides them with ample time to do so while recognizing the urgent need to ensure that all QHP enrollees have access to adequate networks that will provide them with access to Essential Health Benefits.

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.⁴⁰ Some states have adopted provisions that apply broadly to private carriers in their state, including those participating in a State Exchanges or SBE-FP, while in other cases, State Exchanges and SBE-FPs have adopted their own standards for participating providers, and in some states, both broader state network adequacy standards and Exchange-specific provisions apply.⁴¹ The result is a confusing patchwork for QHP enrollees, which has too often resulted in lack of access. The proposed change to establish a federal minimum standard for network adequacy is sorely needed.

Further, we commend HHS's proposed approach that state reviews must do more than rely on the attestation of plans as to their compliance with network adequacy standards. 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.⁴² Requiring states to test whether plan networks comply with the standards is a crucial component to ensuring the adequacy of those networks, and these 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. Moreover, experience from both federal and state programs has demonstrated that a layered approach to measuring and monitoring 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.⁴³ This is especially important given, as HHS recognizes, the

⁴⁰ 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 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>.

⁴¹ See 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.

⁴² See, e.g., *id.*; Weber, *supra* note 40.

⁴³ 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>.

proliferation of QHPs that employ narrow networks, and even ghost networks.⁴⁴ Scrutiny is needed to ensure that QHP networks provide adequate and timely access to Essential Health Benefits. We appreciate that HHS is taking important steps in this proposed rule to ensure that QHP enrollees in State Exchanges and SBE-FPs will be able to rely on a minimum level of access.

We support HHS's leaving the states with room to hold QHPs to higher standards, reflecting the particular needs of each state, while maintaining a national floor for network adequacy. The current approach to network adequacy standards has resulted in consumer protections varying widely across state lines. A federal minimum standard that will apply to all QHP issuers in all Exchanges will go a long way toward addressing the shortcomings of the current patchwork approach.

§ 155.1312 – State public notice requirements and § 155.1320 – Monitoring and Compliance

We support the proposal to allow states seeking a § 1332 waiver to conduct public hearings and post-award forums in a virtual or hybrid format. This change would help more people – especially those with limited mobility, caregiving responsibilities, and poor access to transportation – weigh in on their state's policy decisions. However, clearer guidance is needed to ensure that virtual meetings are accessible. In the final rule we encourage HHS to codify practices that are essential to ensuring access for and communication with people with disabilities, people with limited English proficiency, and people with limited broadband access. Such practices may include closed captioning, simultaneous interpretation, allowing people to dial in to meetings, and ensuring that the technology used is compatible with assistive technologies used by people with disabilities.

⁴⁴ See, e.g., Julie Appleby, *The Big Squeeze: ACA Health Insurance Has Lots of Customers, Small Networks*, NPR SHOTS, Apr. 5, 2023 5:01 am, <https://www.npr.org/sections/health-shots/2023/04/05/1168088923/the-big-squeeze-aca-health-insurance-has-lots-of-customers-small-networks>; Evan Sweeney, Fierce Healthcare, *ACA Exchanges Still Dominated by Narrow Network Plans* (2018), <https://www.fiercehealthcare.com/payer/aca-exchanges-still-dominated-by-narrow-network-plans>; Erica Hutchins Coe et al., McKinsey, *Hospital Networks: Perspective from Four Years of the Individual Market Exchanges* (2017), <https://www.mckinsey.com/industries/healthcare/our-insights/hospital-networks-perspective-from-four-years-of-the-individual-market-exchanges>; Abigail Burman, *Laying Ghost Networks to Rest: Combatting Deceptive Health Plan Provider Directories*, 40 YALE L. & POL'Y REV. 78 (2021-2022).

§ 156.111 – State selection of EHB- benchmark plans for plan years beginning on or after January 1, 2020

HHS proposes to streamline the EHB benchmarking process through three policies: consolidating the three current benchmark options; eliminating the requirement for states to submit a drug formulary in situations when the state is not requesting changes to their prescription drug EHB; and replacing the generosity limit with a limit based on the most generous typical employer plan. NHeLP fully supports all three proposals. We believe the first two proposals are simple fixes that will reduce the burden on states to request changes to their EHB benchmark plans and we fully support their adoption.

We also support HHS’s proposal to replace the generosity limit with an actuarial range as determined by typical employer plans. First, we note that we disagree with HHS’s statement that the current rule establishes a floor based on actual equivalence to a typical employer plan. We believe such a narrow reading of the ACA’s typical employer plan provision is not in line with the purpose of the law. When the ACA was enacted, it was common for private plans, including employer plans, to exclude certain services that are now considered essential from coverage. The ACA’s EHB requirement was adopted precisely to close those gaps in coverage. It would make little sense for the ACA to require full equivalence with typical employer plan coverage if the goal of the law is to ensure and improve access to a broad range of minimum essential benefits.

Instead of full equivalence, therefore, we believe a more harmonious reading of the ACA would require EHB coverage that is either “no less than” the scope of coverage in a typical employer plan, or “within the general range” of the scope of coverage in typical employer plans. The former was the interpretation many stakeholders, including actuaries and states, adopted in pursuing changes to their benchmark plans under the current rules.⁴⁵ That interpretation has allowed eleven states to adopt new coverage

⁴⁵ See, e.g., State of South Dakota, *Essential Health Benefits: Analysis of 2021 Benchmark Plan Options* 6 (June 2019) (finding that “Since our recommendation is to retain the 2017 South Dakota EHB benchmark plan for 2021 augmented with the coverage of ABA therapy for ASD treatment, we simply needed to add the value of that benefit to the value previously determined for the 2017 EHB plan...Thus, the test that the proposed plan provide a scope of benefits equal to, or greater than, the scope of benefits provided under a typical employer plan...is automatically met.”) See also Illinois Dep’t of Insurance, *EHB Benchmark Analysis with a Focus on the Opioid Epidemic 2–3* (June 2018) (finding that “The first requirement states the EHB benchmark plan must be equal to or greater than the scope of benefits provided under a typical employer plan. The starting point for the proposed benchmark is the current 2019 benchmark, which is one of the most popular small group plans offered in Illinois...The DOI has elected to

requirements in an effort to reduce health disparities and address long-standing health care needs among their populations. A reading of the current rule that requires full equivalence hampers states' ability to propose a benchmark plan that addresses those health care needs by narrowing down the actuarial room states can navigate.

Thus we are pleased to see HHS now propose using a general range to meet the typical employer plan requirement. This proposed reading accounts for the increasing variability in employer plan coverage by allowing states to choose the least generous option as the floor and the most generous option as the ceiling. In addition, this reading has the ultimate effect of adding a new option to the range of possibilities that would make up the most generous plan: the largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the state. That option represents the only difference between what are today the options for typical employer plan equivalence (floor) and the generosity limit (ceiling). We believe adding this new plan option as a ceiling would expand states' ability to adopt necessary changes in EHB coverage because large group plans tend to be more generous than some of the previous ten options.

We note that we continue to have concerns with the benchmarking approach because the ACA did not authorize HHS to defer the authority to define EHBs to states. Congress' clear intention in passing the ACA was to have the HHS Secretary establish standardized rules for a minimum set of EHBs that would be uniform across all jurisdictions. The benchmark approach, however, has led to vast inconsistencies in coverage across states and has enabled plans to maintain significant gaps in place.⁴⁶ Many times, these gaps have a disproportionate impact on Black, Indigenous, and People of Color (BIPOC), Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals, individuals with disabilities, and other underserved communities. We recognize, however, that HHS can set rules to make the benchmarking process a viable

add five benefits or criteria to the 2019 benchmark plan. Since the DOI is enhancing the plans, the proposed benchmark continues to meet the criteria of the first requirement.”).

⁴⁶ See, e.g., Lauren Lipira, et al., *Evaluating the Impact of the Affordable Care Act on HIV Care, Outcomes, Prevention, and Disparities: A Critical Research Agenda*, 28 J. HEALTH CARE FOR POOR & UNDERSERVED 1256 (2017), <https://muse.jhu.edu/article/677348/pdf> (finding “wide variation in coverage of EHBs across plans,” and that benchmark prescription drug coverage does not guarantee coverage of the most appropriate anti-retroviral therapy). See also Stacey A. Tovino, *State Benchmark Plan Coverage of Opioid Use Disorder Treatment and Services: Trends and Limitations*, 70 S.C.L. REV. 763 (2019) (finding that the vast majority of state benchmark plans are either silent or explicitly exclude methadone for opioid use disorder treatment).



tool to achieve health equity and address unmet health needs. The current benchmarking options, coupled with HHS’s policy around defrayal, allow states to improve EHB coverage by adding new benefits within the actuarial limit.

Because the effect of HHS’s proposal to implement an actuarial limit based on the least and most generous typical employer plan is to potentially increase the actuarial ceiling even further, the proposal will enable states to use EHB benchmarking as a health equity tool that also appropriately balances potential increases in costs to consumers. As we have expressed in various letters submitted to HHS and CCIIO, we firmly believe HHS should still address gaps in coverage that are significantly contributing to health disparities by establishing or improving coverage standards at the federal level for categories such as maternal and newborn care, mental health and SUD services, and rehabilitative and habilitative services and devices.⁴⁷ In fact, we believe both the ACA and the need for equity require establishment of national standards. As such, while we support the proposals in the 2025 NBPP, we plan to continue engaging in conversations with federal officials about the need for more action at the federal level.

Finally, we note that, as HHS asserts, the proposal to change absolute equivalence to a range of typical employer plan scope of benefits may have the potential effect of reducing the administrative burden on states and therefore incentivize states to seek benchmark changes, although it is unclear how much the burden will actually be reduced. Under HHS’s proposal, states still have to examine the generosity of benefits provided by the same number of plans as it did before, in order to determine which plans are “most” or “least” generous. However, it appears the burden on states is reduced overall due to states no longer being required to complete one last, additional step required by the existing rule: to “assess the value of each typical employer plan option to identify an exact match for the expected value offered by the proposed plan.”⁴⁸ Allowing states to skip this final step of finding an already-existing “exact match” would likely reduce the administrative burden in developing an EHB-benchmark plan.

⁴⁷ For more information, see Nat’l Health Law Prog., *Letter to Sec. Becerra, Re: Advancing Health Equity Through Essential Health Benefits* (Dec. 6, 2021), <https://healthlaw.org/resource/nhelp-letter-to-hhs-sec-becerra-re-advancing-health-equity-through-essential-health-benefits>; Nat’l Health Law Prog., *Letter to CCIIO Director Ellen Montz, Re: Request for Modifications to the Federal Prescription Drug and Maternity Care Essential Health Benefits Standards* (Aug. 19, 2022), <https://healthlaw.org/resource/nhelp-letter-to-cciio-director-ellen-montz-re-request-for-modifications-to-the-federal-prescription-drug-and-maternity-care-essential-health-benefit-standards/>.

⁴⁸ 88 Fed. Reg. 82594.



Nonetheless, we believe this assertion would benefit from further clarity and guidance from HHS regarding the specific analysis states must perform of each typical employer plan. For example, if states have to assess the value of all potential typical employer plans to determine the least and most generous plan in the same way that they assess the value to determine equivalence today, then the burden is likely to remain the same. However, if the actuarial evaluation to determine the least and most generous plan is significantly different and less burdensome than an equivalence analysis, then the proposal has the potential of considerably reducing the administrative burden imposed on states. Importantly, our support for this policy does not depend on this final point regarding administrative burden. In the worst-case scenario, states must go through the same amount of work but now have more actuarial room to expand access to necessary services and address unmet health needs.

§ 156.115 – Provision of EHB

HHS proposes to remove the prohibition on non-pediatric oral health services as EHB. We strongly support this proposal and urge HHS to go further and rescind § 156.115(d) entirely. We have long held that prohibiting benefits described in § 156.115(d) is not required by the ACA. Moreover, the prohibition on routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia unduly restricts states seeking to update their EHB benchmark plans. The regulation is also at odds with the ACA requirement that HHS periodically review and update EHB. By removing the regulatory prohibition on adult dental and other benefits, HHS will also provide the opportunity for major gains in addressing unmet health needs and advancing health equity.

A. Rescinding the benefits ban is supported by the ACA legislative text and intent

In the ACA, Congress provided for pediatric oral care as part of EHB, but made no mention of oral health services for adults.⁴⁹ Congress also required HHS to periodically review and update the ten EHB categories “to address any gaps in access to coverage or changes in the evidence.”⁵⁰ Factors HHS must examine include whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost,”

⁴⁹ 42 U.S.C. § 18022(b)(1)(J).

⁵⁰ *Id.* at § 18022(b)(4)(H).

and “changes in medical evidence or scientific advancement.”⁵¹ Nothing in the ACA bars HHS from adding adult oral health services pursuant to its EHB review and updating authority. Yet, through regulation, HHS enjoined itself, and states through the benchmarking process, from including adult oral health services as part of EHB.

i. Typical employer plan

In the Proposed Rule, HHS reevaluates its earlier, restrictive reading of the ACA’s requirement that EHB be “equal to the scope of benefits provided under a typical employer plan.”⁵² HHS now says that “a more natural reading of this provision is one that considers all the benefits typically covered by employers.”⁵³ We agree. We note the typical employer plan determination should be informed by surveying “employer-sponsored coverage to determine the benefits typically covered by employers.”⁵⁴ For example, according to the most recent employer plan survey by KFF, among firms offering health benefits in 2023, 90% of small firms and 94% of large firms offer a dental insurance program to their workers.⁵⁵

HHS observes that, based on its own research and comments submitted in response to the EHB RFI, “the scope of benefits in employer-sponsored or other job-based coverage has either remained the same or increased incrementally overall since 2014.”⁵⁶ We agree that health plans subject to EHB coverage standards should not lag behind employer-sponsored coverage.⁵⁷ We also note that small group plans offered by

⁵¹ *Id.* at § 18022(b)(4)(G)(i)(ii).

⁵² 42 U.S.C. § 18022(b)(2)(A).

⁵³ 88 Fed. Reg. 82597.

⁵⁴ 42 U.S.C. § 18022(b)(2)(A).

⁵⁵ KFF, *Employer Health Benefits Annual Survey 2023*, Fig. 217 (Oct. 18, 2023), <https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf>.

⁵⁶ 88 Fed. Reg. 82595.

⁵⁷ In response to the EHB RFI, several commenters reported that employer benefits had become more generous over time. See, e.g., the National Home Infusion Association: “NHIA recommends that CMS delineate outpatient services coverage categories and include home infusion services as essential health benefits. These benefits are nearly universally covered under employer-sponsored plans due to the high value associated with allowing patients needing an IV medication to resume or maintain normal activities while receiving treatment”. Nat’l Home Infusion Assoc., *Comment Letter on Request for Information; Essential Health Benefits* (Jan. 26, 2023), <https://www.regulations.gov/comment/CMS-2022-0186-0175>; Whitman-Walker Health: “An area of employer-sponsored coverage in which there has been substantial change since 2014 is coverage of gender-affirming care for transgender people. According to

employers are subject to EHB requirements. We caution, however, that the ACA's typicality provision should not be read as requiring an apples-to-apples comparison of plans. Moreover, comprehensive EHB coverage should not be dragged down by the vicissitudes of employer coverage, where periods of economic downturn can lead to higher cost sharing and less generous benefits in employer plans.⁵⁸

ii. Excepted benefits

Nothing in the ACA ties EHB to excepted benefits. "Excepted benefits" is a term introduced in the Health Insurance Portability and Accountability Act (HIPAA) to exempt certain plans from the statute's obligations. In its definition of excepted benefits, HIPAA and implementing regulations include limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits "if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan..."⁵⁹ The ACA, however, did not change the definition of excepted benefits nor did it explicitly state that already defined excepted benefits were to be excluded from the definition of EHBs. As a result, a plain reading of the EHB statute and other provisions related to QHPs lends no support to the notion that under no circumstance could vision, dental, and long-term care benefits be considered EHBs.

the Corporate Equality Index (CEI), which has tracked the status of employer-sponsored coverage for this care since 2002, 67 percent of the entire Fortune 500—and 86 percent of all CEI-rated businesses (1,088 of 1,271)—offered employee benefits with no transgender-specific exclusions in 2022 (citation omitted)." Whitman-Walker Health, *Comment Letter on Request for Information; Essential Health Benefits* (Jan. 31, 2023), <https://www.regulations.gov/comment/CMS-2022-0186-0663>. Compare with comments from Cancer Care: "As we will detail in connection with barriers to access due to coverage or cost, private and public employers and plans are desperately seeking ways to lower their cost of providing health care to employees at a time when the costs for that care are increasing. This has created the perfect storm where the scope and generosity of benefits in employer plans has declined, while employees pay more than ever for reduced benefits." CancerCare, *Comment Letter on Request for Information; Essential Health Benefits* (Jan. 31, 2023), <https://www.regulations.gov/comment/CMS-2022-0186-0688>.

⁵⁸ See Héctor Hernández-Delgado & Wayne Turner, Nat'l Health Law Prog., *NHeLP Comments on Essential Health Benefits (EHB) Request for Information (RFI)* 7-10 (Feb. 2, 2023), <https://healthlaw.org/resource/nhelp-comments-on-essential-health-benefits-ehb-request-for-information-rfi/> (explaining the statutory basis for why HHS should use typicality as a guide for minimum coverage levels, and not as a hard cap on EHB).

⁵⁹ 26 U.S.C. § 9832(c)(2)(A); 29 C.F.R. § 2590.732(c)(3).



We also note that the legal basis for rescinding the regulatory prohibition on non-pediatric oral health services also applies to routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia. Because the benefits ban is not supported by the ACA and to allow states to address unmet health care needs, we support rescinding 45 C.F.R. § 156.115(d) in its entirety.

B. Allowing states to add needed benefits will advance health equity.

As HHS notes, rescinding the regulatory prohibition on oral health services for adults (and the other benefits listed in § 156.115(d)) would not require plans to provide such services. By lifting this barrier, state could choose to add adult oral health (and other services) when updating their EHB benchmarking plans. We agree. States are increasingly looking to EHB benchmark updates to address unmet health care needs and help close health disparities. Rescinding § 156.115(d) in its entirety will provide states with the opportunity and flexibility to advance health equity.

i. Rescind the regulatory provision barring EHB adult oral health services

We welcome HHS’s recognition that “[o]ral health and overall health are inextricably linked.”⁶⁰ In a growing consensus, public health officials are calling for the end of outmoded and incongruous segregation of oral health care. In 2009, the World Health Organization (WHO) Global Conference on Health Promotion issued a call for the integration of oral health services and primary care.⁶¹ Evidence overwhelmingly demonstrates that oral health care is a critical, essential part of health care.

The option for states to include routine adult dental care in their Marketplace plans has the potential to improve health outcomes and improve quality of life for many. In 2000, a report titled *Oral Health in America: Advances and Challenges* concluded, [t]he mouth is the center of vital tissues and functions that are critical to total health and well-being across the lifespan.”⁶² Now, more than twenty years later, we know even more about

⁶⁰ 88.Fed Reg. 82597.

⁶¹ Kwan S Petersen, *The 7th WHO Global Conference on Health Promotion-towards integration of oral health* (Nairobi, Kenya 2009), Community Dental Health 2010; 27(Suppl 1):129–36, <https://www.cdjournal.org/issues/27-3-june-2010-supplement-1/274-the-7th-who-global-conference-on-health-promotion-towards-integration-of-oral-health-nairobi-kenya-2009?downloadarticle=download>.

⁶² Nat’l Insts. of Health, *Oral Health in America: Advances and Challenges*. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health,



the importance of oral health to whole body health. Yet, routine dental care remains unreachable for many in the United States. This leads to unnecessary physical and mental suffering, loss of productivity, and higher health care costs.

a. State of Dental Health and Care

The state of oral health in the United States clearly indicates the need for access to routine dental care. Dental caries, also known as cavities, are a prevalent condition among adults. According to the Centers for Disease and Prevention (CDC) between 2015 and 2018, 25.9% of adults ages 20-44 had untreated dental cavities and 25.3% of adults ages 45-64 had untreated dental cavities.⁶³ On average, adults have about 9 permanent teeth decayed, missing, or filled due to dental disease.⁶⁴

About half of all adults ages 30 and older showed signs of periodontal disease, also known as gum disease, and severe periodontal disease, also known as periodontitis, affects about 9% of adults.⁶⁵ Periodontal disease is an oral infection that inflames the gums and effects the supporting structures of the teeth. This can lead to bleeding gums, pain, and tooth loss.⁶⁶ Periodontitis may link to chronic diseases like cardiovascular disease, diabetes, respiratory disease, and some cancers.⁶⁷ Periodontitis may also exacerbate other health conditions like Alzheimer's disease.⁶⁸

Oral health conditions affect an individual's physical health and affects mental well-being and ability to interact socially. Oral health is not just the physical state of teeth and gums but also includes the ability to speak, eat, smile, and more.⁶⁹ These fall into the category of quality-of-life metrics like functional factors, psychological factors, social

National Institute of Dental and Craniofacial Research 3A-2 (2021), <https://www.nidcr.nih.gov/sites/default/files/2021-12/Oral-Health-in-America-Advances-and-Challenges.pdf#page=313>.

⁶³ Ctrs. for Disease Control and Prevention, *Oral and Dental Health*, FastStats <https://www.cdc.gov/nchs/fastats/dental.htm>.

⁶⁴ Nat'l Insts. of Health, *supra* note 62 at 3A-2.

⁶⁵ Ctrs. for Disease Control and Prevention, *supra* note 63.

⁶⁶ Nat'l Insts. of Health, *supra* note 62.

⁶⁷ *Id.*; Am. Acad. of Periodontology, *Gum Disease and Other Diseases*, <https://www.perio.org/for-patients/gum-disease-information/gum-disease-and-other-diseases/>.

⁶⁸ *Id.*

⁶⁹ Nat'l Insts. of Health, *supra* note 62.



factors, and the existence of discomfort or pain.⁷⁰ Dental conditions are responsible for decreasing these quality-of-life metrics as they cause pain, functional, aesthetic, nutritional, and psychological issues. Dental conditions, including pain, can lead to chewing problems that can lead to less food intake, insomnia, irritability, and low self-esteem. About 42% of low-income adults and 30% of middle-income adults reported experiencing difficulty biting and chewing while 43% of low-income adults and 27% of middle-income adults reported experiencing pain either very often or occasionally.⁷¹

Further, problems due to dental conditions can lead to avoiding smiling, a key method of interaction, with 37% of low-income adults and 24% of middle-income adults reporting that they avoid smiling either very often or occasionally.⁷² Adults also reported feelings of embarrassment and anxiety about their dental condition. About 35% of low-income adults and 21% of middle-income adults reported feeling embarrassment and 30% of low-income adults and 18% of middle-income adults reported anxiety either very often or occasionally.⁷³

Almost 18% of working-age adults reported that the appearance of their mouth and teeth affects their ability to interview for a job.⁷⁴ One study researched the association between untreated cavities and missing anterior teeth on employment. They constructed a dental problem index using tooth count and tooth surface condition. The researchers found that a one-point increase in the dental problem index resulted in a decrease in the odds of being employed by 7.7% and having a routine dental visit significantly impacted the dental problem index.⁷⁵

In terms of dental care utilization among adults ages 18-64, the CDC found that between 2019 and 2020, the percentage of adults who received a dental visit decreased

⁷⁰ J.C. Spanemberg, J.A. Cardoso, E.M.G.B. Slob, & J. López-López, *Quality of life related to oral health and its impact in adults*, *Journal of Stomatology*, 120 ORAL AND MAXILLOFACIAL SURGERY, 234–329 (2019),

<https://www.sciencedirect.com/science/article/abs/pii/S2468785519300473>.

⁷¹ Am. Dental Assoc., Health Policy Inst., *Oral health and well-being in the United States*, <https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/hpi/us-oral-health-well-being.pdf>.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Yara A. Halasa-Rappel et al., *Broken smiles: The impact of untreated dental caries and missing anterior teeth on employment*, 79 J. PUBLIC HEALTH DENT. 231–237 (2019), <https://pubmed.ncbi.nlm.nih.gov/30990228/>.

across income levels, sex, and racial groups.⁷⁶ In 2022, about 64% of adults ages 18 and over had a dental exam or cleaning in the past year.⁷⁷ Even when considering the effects of COVID-19 in dental care utilization among adults between 2020 and 2023, there has not been an increase to the rate of dental care utilization in 2019.⁷⁸ Previous research also indicates that income and health insurance status are important predictors of unmet dental needs that result in losing teeth and gum disease.⁷⁹ This research demonstrated that unmet dental needs are effected by the oral health care policies in their state. The researchers indicate that improvements to state and federal oral health program could greatly improve oral health.⁸⁰

b. Oral health during pregnancy

Pregnant people are particularly at risk for oral health conditions. The American Dental Association notes that oral health conditions that can arise or worsen include cavities or caries that may increase due to changes in diet and increased acidity and erosion from vomiting;⁸¹ and a condition called Pyogenic granuloma or oral pregnancy tumor.⁸² In addition, according to the CDC, approximately 60-75% of pregnant women have gingivitis, which is an early state of periodontal disease that can be worsened due to

⁷⁶ Ctrs. for Disease Control and Prevention, *supra* note 63.

⁷⁷ Jeannine S. Schiller & Tina Norris, Nat'l Ctr. for Health Statistics, *Early Release of Selected Estimates Based on Data From the 2022 National Health Interview Survey* (2022), <https://www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease202304.pdf>.

⁷⁸ Nat'l Ctr. for Health Statistics, *Percentage of having a dental exam or cleaning in the past 12 months for adults aged 18 and over, United States, 2019–2022* National Health Interview Survey, Generated interactively: Dec 15 2023 from https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html.

⁷⁹ D.J. Gaskin et al., *Predictors of Unmet Dental Health Needs in US Adults in 2018: A Cross-Sectional Analysis*, 7 JDR CLINICAL & TRANSLATIONAL RESEARCH 398–406 (2022), <https://journals.sagepub.com/doi/10.1177/23800844211035669>.

⁸⁰ *Id.* J.S. Feine, *Oral Health Care Access, Inequity, and Inequality*, 7 JDR CLIN TRANS RES. 332–333 (2022).

⁸¹ Am. Dental Assoc., *Pregnancy* (2021), <https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/pregnancy>.

⁸² Shailesh M. Gondivkar, Amol Gadvail, & Revant Chole, *Oral pregnancy tumor*, 1 CONTEMP CLIN DENT. 190–192 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3220110/>.

changing hormones during pregnancy.⁸³ Similarly, approximately 40% of pregnant women have some form of periodontal disease.⁸⁴

While the connection between periodontal disease and poor pregnancy outcomes requires more research, a link between the two is likely.⁸⁵ One study performed a systematic review of the research associated with periodontal disease and adverse birth outcomes, including maternal mortality, preterm birth, and perinatal mortality. Of those factors, the researchers found an association between periodontal disease and preterm birth, low-birth weight, preeclampsia, and preterm low-birth weight.⁸⁶

Pregnant people are also less likely to receive dental care. Approximately 46% of pregnant women in the U.S. report having dental cleaning during their pregnancy and this number varies depending on socioeconomic factors. Thirty-six percent of pregnant women report that it has been more than a year since their routine dental visit, and 28% note that they have not received routine dental care in at least two years.⁸⁷ This study also found that many pregnant women who avoid routine dental care are concerned about the cost. By delaying routine dental care, potential dental issues are likely to worsen meaning higher cost, potential pain, and more intensive treatment.⁸⁸

c. Racial disparities

Racial and ethnic disparities persist in adult access to dental care. Recent national data shows that African American and Mexican American adults are more likely to have

⁸³ Ctrs. for Disease Control and Prevention, *Pregnancy and Oral Health*, <https://www.cdc.gov/oralhealth/publications/features/pregnancy-and-oral-health.html> (last visited Dec. 20, 2023). These comments will occasionally use the terms “women” or “woman” as well as other gendered language where the research data or laws cited uses those specific terms. We recognize that people of different genders, gender identities, and expressions can become pregnant and need access to care. As such, we have tried to otherwise limit our use of gendered language where possible.

⁸⁴ Susan Lieff et al., *The oral conditions and pregnancy study: periodontal status of a cohort of pregnant women*, 75 *J Periodontol*, 116–126 (2004), <https://pubmed.ncbi.nlm.nih.gov/15025223/>.

⁸⁵ Ctrs. for Disease Control and Prevention, *supra* note 63.

⁸⁶ L.A. Daalderop et al., *Periodontal Disease and Pregnancy Outcomes: Overview of Systematic Reviews*, 3 *JDR CLIN TRANS RES.* 10–27 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6191679/>.

⁸⁷ *Id.*

⁸⁸ *Id.*

untreated tooth decay and moderate to severe periodontitis compared to white adults.⁸⁹ Researchers investigated the effects of Medicaid adult dental coverage expansions and found that racial and ethnic disparities decreased after the recent Medicaid expansion of extensive dental care. Expansion in coverage led to an 8% increase in the likelihood of receiving dental care. Researchers noted that this represents a reduction in pre-expansion disparities by 75% for non-Hispanic Black adults and 50% for Hispanic adults.⁹⁰ While no similar studies exist in Marketplace coverage, we expect that QHP enrollees would experience similar reductions in racial and ethnic disparities if states adopt coverage of routine adult dental care.

d. Cost of dental care

Other studies have also shown that dental care is expensive and inaccessible for many people. The Health Policy Institute (HPI) for the American Dental Association found that while dental insurance coverage was expanding (uninsured working-age adults reduced from 34% to 27%), cost is still an important barrier for accessing dental care.⁹¹ HPI found that the top three reported barriers for not obtaining dental care were financial reasons such as “could not afford the cost,” “insurance did not cover the procedure,” and “did not want to spend the money.”⁹²

Because oral health services have been excluded from EHB coverage for adults, many people cannot access such services.⁹³ According to the Oral Health and Well-Being Survey, cost was almost three times more likely to be reported as a reason for foregoing care than the second most common reason. Further, among adults who had not visited

⁸⁹ L.N. Borrell & D.R. Williams, *Racism and oral health equity in the United States: Identifying its effects and providing future directions*, 82 J PUBLIC HEALTH DENT. 8–11 (2022).

⁹⁰ G.L. Wehby, W. Lyu, D. Shane, *Racial And Ethnic Disparities In Dental Services Use Declined After Medicaid Adult Dental Coverage Expansions*, 41 HEALTH AFF. 44–52 (2022), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01191>.

⁹¹ Niodita Gupta & Marko Vujicic, Am. Dental Assoc., Health Policy Inst., *Barriers to dental care are financial among adults of all income levels* (2019), https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/hpi/hpibrief_0419_1.pdf.

⁹² *Id.*

⁹³ Marko Vujicic, Thomas Buchmueller, & Rachel Klein, *Dental Care Presents the Highest Level of Financial Barriers, Compared to Other Types of Health Care Services*, 35 HEALTH AFF. 2176–2182 (2016), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0800>.

the dentist within the past year, fifty-nine percent noted cost as the reason.⁹⁴ Finally, this study found that cost was the most significant factor preventing Americans from accessing dental care irrespective of age, income level, and type of insurance.

e. Adult dental care effects on children

A pregnant person's oral health may have longer term effects on their child throughout their life. For example, children of mothers who have high levels of untreated cavities are more than three times as likely to have more cavities than children whose mothers had no untreated cavities.⁹⁵ In addition, high levels of cariogenic bacteria in mothers can lead to increased cavities in their infants.⁹⁶ This relationship has also been observed with a mother's tooth loss and their child's cavities. For these reasons, researchers have concluded that mothers' oral health is a strong predictor of their baby's oral health and that this effect can be compounded well into childhood.⁹⁷ Children with oral health concerns are almost three times more likely to miss school because of dental pain.⁹⁸

This effect also has the potential to expand into adulthood. One study had mothers rate their own oral health. The children of mothers who rated their oral health as poor were more likely to grow up with worse oral health than those of mothers who rated their oral health as good. This study concludes that a mother's self-rated oral health should be considered a risk indicator for poor oral health in their children later in adulthood.⁹⁹ Further, other studies show that a mothers' perception of her oral health and her oral health behavior had an impact on the dental health of their children and their children's perception of dental care.¹⁰⁰

⁹⁴ *Id.*

⁹⁵ J. Shahangian, *Brushing for Two: How Your Oral Health Affects Baby*, <https://www.healthychildren.org/English/ages-stages/prenatal/Pages/Brushing-for-Two-How-Your-Oral-Health-Effects-Baby.aspx> (last visited Dec. 20, 2022).

⁹⁶ *Id.*

⁹⁷ Bruce A. Dye et al., *Assessing the relationship between children's oral health status and that of their mothers*, 142 J AM DENT ASSOC. 173–183 (2011), [https://jada.ada.org/article/S0002-8177\(14\)61498-7/fulltext](https://jada.ada.org/article/S0002-8177(14)61498-7/fulltext).

⁹⁸ Ctrs. for Disease Control and Prevention, *supra* note 63.

⁹⁹ D.M. Shearer et al., *Maternal oral health predicts their children's caries experience in adulthood*, 90 J DENT RES. 672–677 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3144114/>.

¹⁰⁰ Jana Olak et al., *The influence of mothers' oral health behavior and perception thereof on the dental health of their children*, 9 EPMA J. 187–193 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5972135/>.

f. Coverage of adult dental care

Employers have expanded coverage of adult dental care to the point that is reasonable to conclude that such services are part of typical employer plans. Kaiser Family Foundation found that more than 90% of employers offered a dental insurance program to their employees and about 60% of employers made contributions toward the cost of coverage.¹⁰¹ Dental care is covered under most Medicaid programs and by many employers. It is imperative that the gap in dental care be closed by removing the prohibition on routine non-pediatric dental care.

Some issuers may object to lifting the prohibition on adult oral health services, for example, by citing to implementation challenges including establishing new provider networks.¹⁰² Such concerns should be raised in comments if a state decides to update its EHB base benchmark plan to include non-pediatric oral health services.¹⁰³ However, we believe predicted operational challenges may be overblown and should not prevent HHS from removing the unwarranted regulatory prohibition on non-pediatric oral health services.

ii. Rescind the provision barring EHB non-pediatric eye exam services

In the U.S., vision loss is a significant issue facing adults.¹⁰⁴ Approximately seven million people are living with visual impairment or blindness in the U.S.; and, among those seven million people, 1.62 million people with visual impairment and/or blindness were younger than forty years old.¹⁰⁵ Racial and ethnic communities are at higher risk for various diseases and subsequent vision impairment and blindness.¹⁰⁶ For example, Black individuals are 2.8 times more likely than white individuals to experience vision

¹⁰¹ Gary Claxton et al., Kaiser Fam. Found., *Employer Health Benefits Survey 2023 Annual Survey* 55 (2023), <https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf>.

¹⁰² 88 Fed. Reg. 82598.

¹⁰³ 45 C.F.R. § 156.111(c).

¹⁰⁴ Abraham D. Flaxman et al., *Prevalence of Visual Acuity Loss or Blindness in the US: A Bayesian Meta-analysis*, 139 JAMA OPHTHALMOLOGY 717 (2021).

¹⁰⁵ *Id.*

¹⁰⁶ Angela R. Elam et al., *Disparities in Vision Health and Eye Care*, 129 OPHTHALMOLOGY 89 (2022).



impairment and blindness.¹⁰⁷ In addition, Hispanic older adults and other racial/ethnic communities use low-vision devices at lower rates than white people.¹⁰⁸

By 2050, the number of people with vision conditions is expected to double with approximately twenty-five million people with blindness and visual impairment.¹⁰⁹ Researchers predict that Black/African–Americans will experience higher rates of vision impairment than other non-Hispanic white individuals, women, and older adults.¹¹⁰ This increase is due the expected increase in chronic diseases that can cause vision loss, such as diabetes, as well as an aging population.¹¹¹ Diabetic retinopathy is the leading cause of severe vision loss and blindness, and one out of three Americans with diabetes will develop diabetic retinopathy, disproportionately affecting Black individuals at a higher rate.¹¹²

Along with diabetic retinopathy, glaucoma is also one of the leading causes of irreversible blindness in the U.S.¹¹³ By 2050, studies project that the three million people currently living with the disease will increase to 6.3 million.¹¹⁴ Similarly, cataracts in one or both eyes can occur at any age and will also increase in number as the population increases in 2050.¹¹⁵ Other causes of vision impairment are primarily age-related eye diseases, such as diabetic retinopathy, glaucoma, age-related macular degeneration, cataracts; and other causes include amblyopia and strabismus.¹¹⁶

Preventive vision and eye care is essential. A comprehensive eye exam by an optometrist or ophthalmologist is crucial for early detection and treatment, so that common eye diseases do not result in permanent vision loss or blindness. Although eye

¹⁰⁷ Diana E. Fisher et al., *Visual Impairment in White, Chinese, Black, and Hispanic Participants from the Multi-Ethnic Study of Atherosclerosis Cohort*, 22 *OPHTHALMIC EPIDEMIOLOGY* 321 (2015).

¹⁰⁸ Elam, *supra* note 106.

¹⁰⁹ Rohit Varma et al., *Visual Impairment and Blindness in Adults in the United States: Demographic and Geographic Variations from 2015 to 2050*, 134 *JAMA OPTHALMOLOGY* 802 (2016).

¹¹⁰ Flaxman, *supra* note 104.

¹¹¹ *Id.*

¹¹² *Id.*; Elam, *supra* note 106.

¹¹³ Ctrs. for Disease Control and Prevention, *Vision Health Initiative (VHI): Common Eye Disorders and Diseases* (2023), (last visited Dec. 17, 2023), https://www.cdc.gov/visionhealth/basics/ced/index.html#diabetic_retinopathy.

¹¹⁴ Varma, *supra* note 109.

¹¹⁵ *Id.*

¹¹⁶ Ctrs. for Disease Control and Prevention, *supra* note 63.



diseases are very common, they tend to go unnoticed. Some eye diseases do not have symptoms at first, so having access to regular and consistent preventive vision care, such as comprehensive dilated eye exams for adults, can detect eye diseases early and address some of the leading causes to vision impairment. Routine eye exams for adults can also help address other health conditions. For example, people with vision loss are more likely to report depression, hearing impairment, stroke, falls, cognitive decline, and premature death.¹¹⁷ Vision impairment also decreases a person's ability to engage in social activity, substantially compromising their overall quality of life.¹¹⁸

Many people have trouble accessing routine eye exams and vision care. Data show that low-income patients have fewer outpatient ophthalmologic visits than higher income patients along with not being able to afford eyeglasses.¹¹⁹ People living with vision impairment report having more problems in accessing care, most notably the cost of insurance coverage, but also transportation issues and refusal of services by providers.¹²⁰ Due to lack of coverage, many people seek eye examinations only after significant vision problems have developed.¹²¹ Because the leading factor preventing access to eye exams and vision care is lack of insurance coverage, HHS can open the door to coverage and access to health services many consider essential – needed eye care – by removing the prohibition on non-pediatric eye exams as EHB.¹²²

iii. Rescind the provision banning EHB long-term/custodial nursing home care benefits

HHS seeks comments on whether to rescind the prohibition on long-term/custodial nursing home care benefits as EHB. We support removing this along with the other provisions in § 156.115(d). However, the vague and overly broad wording of the regulatory text makes it difficult to assess the impact, if any, of the EHB prohibition.

¹¹⁷ David B. Rein et al., *The economic burden of major adult visual disorders in the United States*, 124 JAMA OPHTHALMOLOGY 1754 (2006).

¹¹⁸ Brad Wong et al., *The case for investment in eye health: systematic review and economic modelling analysis*, 101 BULLETIN WORLD HEALTH ORGANIZATION 786 (2023).

¹¹⁹ Elam, *supra* note 106.

¹²⁰ *Id.*

¹²¹ Peter Shin and Brad Finnegan, *Assessing the need for on-site eye care professionals in community health centers*, in 22 HEALTH POLICY AND MANAGEMENT ISSUE BRIEFS 16–18 (2009).

¹²² Mapa Piyasena et al., *Systematic review on barriers and enablers for access to diabetic retinopathy screening services in different income settings*, 14 PLOS ONE e0198979 (2009).

In the 2012 rule promulgating § 156.115(d), HHS links the prohibited benefits to traditionally excepted benefits.¹²³ This statement within the 2012 Proposed Rule then references the following citation: “For more information on excepted benefits, see 26 CFR 54.9831–1, 29 CFR 2590.732, 45 CFR 146.145, and 45 CFR 148.220”; therefore, it appears HHS is referencing the definition of “long-term care benefits” included within the cited sources. However, there is a significant disconnect between the definition of long-term care benefits in the cross-referenced regulations and the language adopted in the final rule prohibiting “long-term/custodial nursing home care benefits.”

It is also unclear whether the prohibition in § 156.115(d) applies exclusively to care provided in institutional settings, or nursing home level services provided in home or community-based settings. Given these ambiguities, we cannot provide meaningful comments on the prohibition or its effects.

As with the other prohibitions in §156.115(d), the statutory language of the ACA does not mandate any express exclusion of “excepted benefits” from EHB. Nevertheless, in addition to EHB nondiscrimination requirements, HHS and states, as well as other covered entities must comply with federal anti-discrimination mandates, including § 504 of the Rehabilitation Act of 1973, as incorporated by § 1557.¹²⁴ Specifically, covered entities under § 1557 are prohibited from providing health programs and services that are more segregated than are appropriate to the needs of people with disabilities, and from employing coverage policies, benefit design, coverage decisions, and other criteria and methods of administration that would do the same.¹²⁵ If a state were to include institutional services such as nursing facility care as an EHB, but exclude home and

¹²³ Dep’t of Health and Human Servs., *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Proposed Rule*, 77 Fed. Reg. 70644, 70651 (Nov. 26, 2012), <https://www.govinfo.gov/content/pkg/FR-2012-11-26/pdf/2012-28362.pdf>.

¹²⁴ 42 U.S.C. § 18022(b)(4); 42 U.S.C. § 18116. See also Brief for Nat’l Health L. Prog. & Disability Rts. Cal. as Amici Curiae Supporting Respondents, *CVS Pharmacy, Inc. v. Doe*, 141 S.Ct. 2882 (2021) (No. 20-1374), <https://healthlaw.org/resource/amicus-brief-from-national-health-law-program-in-cvs-v-doe/>.

¹²⁵ See 45 C.F.R. § 84.4(b)(4) (prohibiting programs and activities which receive Federal financial assistance from utilizing methods of administration that discriminate against individuals with disabilities); 45 C.F.R § 84.4(b)(2) (“aids, benefits, and services . . . [must afford equal opportunity] . . . in the most integrated setting appropriate to the person’s needs.”); *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581 (1999).

community-based services, this would most likely constitute discriminatory benefit design.¹²⁶

As with the other prohibitions in § 156.115(d), the ban on “long-term/custodial nursing” home care as an “excepted benefit” is based on flawed reasoning. If HHS were to place limits or restrictions on long-term care as EHB, it should do so in a way consistent with the ACA and other applicable laws. We urge HHS to engage in a more complete analysis of the intersection of EHB requirements and the integration mandate, to ensure that services are delivered in the most integrated setting appropriate.

§ 156.122 – Prescription drug benefits

We welcome HHS’s proposed changes to EHB prescription drug coverage, and urge the Department to go further to ensure that EHB plan enrollees have access to the prescription drugs they need.

A. A new drug classification system would improve prescription drug coverage and access

HHS seeks further comments on whether to change the drug classification system that serves as the basis for establishing coverage minimums in EHB plans. As we said in our comments responding to the EHB Request for Information (hereinafter “EHB RFI”), the U.S. Pharmacopeia Drug Classification (USP/DC) would be an improvement over the U.S. Pharmacopeia Medicare Model Guidelines (USP/MMG) currently used.¹²⁷ However, the USP/DC still falls short in key areas. As HHS recognizes, and as we explained in previous comments, the USP/DC better reflects the needs of EHB plan enrollees. We have long been concerned that the USP/MMG do not adequately reflect the prescription drug needs of the diverse populations who rely on EHB plans.

The USP/MMG were designed for the Medicare Part D program and its beneficiaries, and therefore do not adequately classify and categorize drugs for the broader populations who rely on health plans subject to EHB standards. The USP/DC uses USP/MMG as the baseline, and then adds additional common outpatient drugs on top of that list. As a result, many of the relics of Part D remain, specifically the exclusion of

¹²⁶ See also, e.g., *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 949 (9th Cir. 2020) (affirming that § 1557 prohibits discriminatory benefit designs); *Doe v. CVS Pharmacy, Inc.*, 982 F.3d 1204, 1211–12 (9th Cir. 2020) (affirming that a beneficiary must have “meaningful access” to a benefit).

¹²⁷ Héctor Hernández-Delgado & Wayne Turner, *supra* note 58, at 7-10.



reproductive and sexual health (RSH) medications and supplies. A significant number of RSH medications are not sufficiently incorporated into the USP DC, particularly medication abortion and contraceptives.

In addition, the USP/DC provides no specific classes or categories of drugs for use in children. For example, Nusinersen and Onasemnogene were recently approved to be used on children as young as two months old for Spinal Muscular Atrophy (SMA) and infantile-onset.¹²⁸ These are the only two FDA-approved drugs to manage SMA in children. However, in the USP/DC, both drugs are included in the broad category “Genetic, Enzyme, or Protein Disorder: Replacement, Modifies, Treatment,” along with 60 other drugs. This category includes drugs that do not treat SMA or relate to any neurological or spinal disease. Thus, these two drugs will likely not be covered by drug company formularies, preventing children from receiving the necessary drugs to treat SMA. Moreover, pediatric patients, including newborns and young children, often require alternatives to taking needed medications in pill form. These can include liquid forms, as well as buccal, nasal, transdermal, and rectal routes.¹²⁹ The USP/DC does not provide for pediatric formulations of prescription drugs approved for adults and children.

Furthermore, the USP/MMG does not include clotting factors and other blood products which are covered under Medicare Part B.¹³⁰ If HHS were to switch to the USP/DC classification system for EHB, the Department should work closely with U.S. Pharmacopeia to close these coverage gaps. As we have stated in previous comments, the current EHB minimum standard for prescription drug coverage is inadequate.¹³¹ HHS should strengthen the standard by requiring a minimum of two drugs per USP class and category. HHS should also adopt the Medicare protected classes requiring coverage of “substantially all” drugs used to treat serious conditions like HIV, where

¹²⁸ See Nat’l Insts. of Health, Spinal Muscular Atrophy: Treatment, <https://www.ninds.nih.gov/health-information/disorders/spinal-muscular-atrophy#:~:text=The%20U.S.%20Food%20and%20Drug,the%20maintenance%20of%20motor%20neurons> (last visited Dec. 13, 2023).

¹²⁹ U.S. Pharmacist, *How Liquids Benefit Adherence for Pediatric Patients* (Nov. 22, 2022), <https://www.uspharmacist.com/article/how-liquids-benefit-adherence-for-pediatric-patients>.

¹³⁰ Letter from American Plasma Users Coalition (A-PLUS) to Marilyn Tavenner, Acting Administrator, CMS, HHS, *Re: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (CMS-9980-P)* (Dec. 21, 2012), <https://www.hemophilia.org/sites/default/files/document/files/A-PLUS%2012.21.12.pdf>.

¹³¹ See, e.g., Nat’l Health Law Prog., Letter to Sec. Becerra, *Re: Advancing Health Equity Through Essential Health Benefits*, *supra* note 47, at 3–5.

treatment regimens can be highly specialized, and covering just one anti-retroviral would not meet the treatment needs of some individuals.

Furthermore, HHS notes that some commenters raised concerns that switching to the USP/DC “could have negative consequences for patients as issuers could be required to cover high-cost drugs with low clinical value.”¹³² This concern is without merit and a red herring designed to block patient access to needed care. If patients were, in fact, relying on treatments with low clinical value, that is not a coverage issue, but a prescriber issue. If providers are indeed prescribing low value treatments, and issuers are approving such treatments via prior authorization, the way to address that problem is not by restricting coverage.

HHS also asks for comments on the administrative burden and potential impact on premiums if issuers were required to follow the USP/DC instead of the USP/MMG.¹³³ We believe the administrative burden and impact on premiums will be minimal. Since the USP/DC is based largely on the USP/MMG, the new classification system will look very much like the system that issuers have used for ten years. Moreover, adding new classes of drugs, such as those used in the treatment of obesity, will lead to cost savings by avoiding adverse health consequences associated with obesity including diabetes, heart disease, hypertension, stroke and cancer.¹³⁴

Finally, HHS asks for comments on newly added medications and the implementation of utilization management strategies, including the clinical coverage criteria for prior authorization or step therapy.¹³⁵ We welcome HHS’s attention to this issue, and urge the Department to require issuers to publicly post the clinical criteria used for prior authorization, step therapy, and other utilization management strategies. Too often, it seems that issuers arbitrarily deny prior authorization requests for medically necessary care. Investigative reporters from *Pro Publica* recently published an exposé on United Healthcare, revealing arbitrary denials of care and a quixotic effort to obtain life-changing medication by a chronically ill young student, labelled by the insurer as high

¹³² 88 Fed. Reg. 82599.

¹³³ 88 Fed. Reg. 82600.

¹³⁴ See, e.g., Alison Sexton Ward, et al., *Benefits of Medicare Coverage for Weight Loss Drugs*, Schaeffer Center for Health Policy & Economics, University of Southern California (April 18, 2023), <https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/>.

¹³⁵ 88 Fed. Reg. 82601.



cost.¹³⁶ A *Washington Post* health and science reporter recounted her own experience jumping through prior authorization hoops to obtain a medication for her three-year-old child diagnosed with juvenile idiopathic arthritis, a chronic immune disorder that, untreated, could lead to disabling joint damage.¹³⁷ The HHS Office of Inspector General (OIG) reviewed Medicaid managed care in Pennsylvania, finding that Keystone First, the commonwealth's largest Medicaid managed care organization (MCO), denied pediatric overnight skilled nursing services based on irrelevant information.¹³⁸ As the OIG report noted, these denials can place the health and safety of the Medicaid enrollee at risk.¹³⁹

These studies and personal accounts represent just a small fraction of evidence showing how health insurers overuse and abuse prior authorization to the detriment of patient health.¹⁴⁰ In the Notice of Benefit and Payment Parameters Rule for Plan Year 2023, HHS strengthened nondiscrimination protections for plans subject to EHB coverage requirements, clarifying that “a non-discriminatory benefit design that provides EHB is one that is clinically-based.”¹⁴¹ In comments, we showed how health insurers

¹³⁶ David Armstrong, et al., *UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings*, Pro Publica (Feb. 2, 2023), <https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis>; Maya Miller, *You Have a Right to Know Why a Health Insurer Denied Your Claim. Some Insurers Still Won't Tell You*, Pro Publica (Nov. 8, 2023), <https://www.propublica.org/article/your-right-to-know-why-health-insurer-denied-claim>.

¹³⁷ Carolyn Y. Johnson, *I wrote about high-priced drugs for years. Then my toddler needed one*, WASH POST (Jan. 3, 2023), <https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/>.

¹³⁸ Dep't of Health & Human Servs., Office of Inspector Gen., *Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization* 6 (2022), <https://oig.hhs.gov/oas/reports/region3/32000201.pdf>.

¹³⁹ *Id.* at 7–8.

¹⁴⁰ Issuers continue to engage in adverse tiering and other discriminatory benefit design practices. See, e.g., Ltr. from Carl Schmid, Executive Director, HIV+Hepatitis Policy Inst. To Dr. Ellen Montz, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight (CCIO), *Re: Substandard & Discriminatory HIV Medication Coverage & Plan Design by Community Health Choice Texas* (Sept. 23, 2023), <https://hivhep.org/testimony-comments-letters/complaint-on-substandard-discriminatory-hiv-medication-coverage-plan-design-by-community-health-choice-texas/>.

¹⁴¹ U.S. Dep't of Health & Human Servs., *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 Final Rule*, 87 Fed. Reg.

routinely and unlawfully discriminate against persons with disabilities or chronic conditions through prior authorization.¹⁴²

HHS should be leading the way to ensure that prior authorization and step therapy criteria, if utilized, are clinically-based and based on generally accepted standards of care. Notably, Washington State recently enacted promising legislation requiring issuers to (1) make prior authorization requirements and restrictions, including written clinical review criteria, available; (2) evaluate and update criteria at least annually; and (3) accommodate new and emerging information related to the appropriateness of clinical criteria with respect to BIPOC and other underserved populations.¹⁴³ We urge HHS to step up monitoring and enforcement of nondiscrimination protections so that enrollees have access to prescription drugs and other essential benefits.

In sum, we support moving to the USP/DC, and urge HHS to take further action to ensure enrollee access to medically necessary prescription drugs. In addition, we renew our call for HHS to develop its own prescription drug classification standards and publications, rather than relying on those developed by private companies.

B. Requiring consumer participation in Pharmacy and Therapeutics Committees will improve the drug review process, but transparency remains in question.

In 2014, we called upon HHS to provide opportunities for health care consumers to participate in EHB Pharmacy and Therapeutics committees (P&T).¹⁴⁴ We support HHS's proposal to include patient-advocates on P&T committees beginning in plan year 2025.

27208, 27390 (May 6, 2022), *codified at* 45 C.F.R. § 156.125(a), <https://www.govinfo.gov/content/pkg/FR-2022-05-06/pdf/2022-09438.pdf>.

¹⁴² Nat'l Health Law Prog., *NHeLP Comments on HHS Notice of Benefit and Payment Parameters for 2023* 20 (Jan. 27, 2022), <https://healthlaw.org/resource/nhelp-comments-on-2023-notice-of-benefit-and-payment-parameters-proposed-rule/>.

¹⁴³ Wash. Sess. Laws E2SHB 1357.SL, May 9, 2023, <https://app.leg.wa.gov/billsummary?BillNumber=1357&Year=2023&Initiative=false>. See also Jane Beyer, Senior Health Policy Advisor, Office of the Insurance Commissioner, *Prior authorization in Washington State*, NAIC Regulatory Framework Task Force 50-72 (Aug. 13, 2023), https://content.naic.org/sites/default/files/national_meeting/RFTF%20Meeting%20Materials%20rev.pdf.

¹⁴⁴ Nat'l Health Law Prog., *Comments on Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016* 20-22 (Dec. 22, 2014), <https://healthlaw.org/resource/nhelp-comments-notice-of-benefit-and-payment-parameters/>.



Health care consumers and patient advocates can provide valuable insights on key policy and coverage issues. However, HHS’s proposal makes no mention of a key component to meaningful participation – transparency.

We reiterate our recommendation from 2014 that HHS should require P&T committees to adhere to minimum transparency requirements, including holding public meetings, providing notice of meeting times, posting the meeting agenda and minutes on the plan’s website so that they are readily and easily accessible for consumers and other stakeholders. Committee by-laws, membership, terms of appointment, and financial disclosure information should all be posted on the plans’ websites and be publicly available. HHS should also require committees to invite comments from plan enrollees and other interested parties.

Patients, plan enrollees, and advocates have long played in key role in policy and advisory boards. For example, Congress established minimum requirements for membership, conflict of interest, and transparency for the Part A Planning Councils under the Ryan White Act, including the requirement that two-thirds of members be clients receiving services.¹⁴⁵ Earlier this year, the Centers for Medicare & Medicaid Services (CMS) proposed a major revamp of requirements for Medical Care Advisory Committees.¹⁴⁶ The proposal includes a requirement that twenty-five percent of Medicaid Advisory Committee members be enrollees.¹⁴⁷ We believe P&T committees in EHB plans should be subject to a similar member ration to help ensure meaningful participation of health plan enrollees.

C. The proposal would end unlawful practices by insurers and pharmacy benefit managers that contribute to gaps in access to prescription drugs.

In the 2013 Final Rule on Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, HHS noted, “plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB.”¹⁴⁸ In 2015, HHS unequivocally stated that when a plan “is covering drugs beyond the number of drugs covered by the [EHB] benchmark, all of these drugs are EHB” and cost sharing paid for drugs properly classed as EHB “must count toward the annual limitation on cost

¹⁴⁵ 42 U.S.C. § 300ff–12.

¹⁴⁶ Ctrs. for Medicare & Medicaid Servs., *Medicaid Program; Ensuring Access to Medicaid Services Proposed Rule*, 88 Fed. Reg. 27960 – 28089 (May 3, 2023), <https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08959.pdf>.

¹⁴⁷ *Id.* at 28,078–79.

¹⁴⁸ 78 Fed. Reg. 12845.



sharing.”¹⁴⁹ And in the EHB RFI, HHS again said that “plans could exceed the minimum number of drugs required to be covered and that additional drugs would still be considered EHB.”¹⁵⁰

Yet despite these clear pronouncements, insurers and pharmacy benefit managers (PBMs) continue to egregiously and unlawfully declare certain, high-cost drugs as “non-EHB” and not subject to the ACA’s cost sharing protections. Such practices remain widespread, and they must stop. We welcome HHS’s proposal to codify this precept in EHB regulations. It should also come as no surprise to regulated entities seeking to evade their obligations to plan enrollees. In our comments responding to the EHB RFI, we provided several examples of insurers declaring certain medications “non-EHB” as a cost-savings measure, but to the detriment of plan enrollees.¹⁵¹

The declaration of certain drugs as “non-EHB” by issuers and PBMs has been characterized by some as the “EHB loophole.”¹⁵² This is a misnomer. There is no loophole. Such practices clearly violate the plain language and legislative intent of the ACA.¹⁵³ The “non-EHB” issue has been raised in ongoing litigation, *Johnson & Johnson Health Care Sys. v. SaveO SP, LLC*, pending in federal district court in New Jersey. As Johnson & Johnson explains in their complaint:

¹⁴⁹ See Patient Protection and Affordable Care Act, 80 Fed. Reg. 10749, 10817 (Feb. 27, 2015), <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

¹⁵⁰ 87 Fed. Reg. 74100. We recognize that HHS may have contributed to the confusion when it suggested in the NBPP 2020 proposed rule that “when a plan covers a brand drug where a generic exists, the brand drug would no longer be considered EHB.” 84 Fed. Reg. 289-290. However, no issuer or PBM can reasonably rely on dicta in the preamble of a proposed rule as a statement of law or administration policy.

¹⁵¹ Héctor Hernández-Delgado & Wayne Turner, *supra* note 58, at 61–62 (citing *2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, Express Scripts, <https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits>); Meghan Pasicznyk, *Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, Evernorth (Oct. 7, 2021), <https://www.evernorth.com/articles/reduce-costs-for-health-care-plans-with-copay-program-assistance>.

¹⁵² See, e.g., Sally Greenberg, *Congress must fix loophole that is costing patients at the pharmacy*, The Hill (July 26, 2021), <https://thehill.com/opinion/healthcare/564821-congress-must-fix-loophole-that-is-costing-patients-at-the-pharmacy/>; Amed Alliance, *Non-Essential Health Benefits and Copay Maximizers*, Amed Alliance, <https://aimedalliance.org/non-essential-health-benefits-and-copay-maximizers/>.

¹⁵³ 42 U.S.C. § 18022(b)(5).



SaveOnSP Program re-categorizes a drug as a non-essential health benefit, it is no longer subject to the ACA's annual out-of-pocket maximum that limits how much patients with private insurance can be required to pay for their medical care each year. The out-of-pocket maximum rule is meant to prevent patients from being forced to choose between vital medication and other necessities of life, such as food, clothing and housing. In direct contravention to this legislative intent, by reclassifying certain medications as nonessential health benefits, the SaveOnSP scheme allows the payer to continue to charge the patient inflated copay costs even where the patient has already satisfied their out-of-pocket maximum.¹⁵⁴

The court has allowed the case to proceed, ruling against Save On's motion to dismiss.¹⁵⁵ While the case is pending, and in the absence of enforcement of ACA protections by HHS, Johnson & Johnson has urged state regulators to take action. In comments to the Pennsylvania Department of Insurance, the company wrote,

[t]he discretion afforded to PBMs and health plans to determine which therapies are non-essential has created a system in which any medication, without regard to its actual medical necessity or its impact on patient health and safety, can be deemed by a PBM as "non-essential" to the detriment of patients and their continuity of their care.¹⁵⁶

The SaveOnSP program has been adopted by a broad range of employers, to the detriment of employees and their families.¹⁵⁷ For example, Iona University, which introduced SaveOnSP in 2019, touts:

¹⁵⁴ *Johnson & Johnson Health Care Sys. v. Save On SP, LLC*, CA No. 22-2632, Complaint ¶10 (May 4, 2022), <https://www.drugchannelsinstitute.com/files/22-cv-02632.pdf>.

¹⁵⁵ *Id.* Opinion and Order (Jan. 1, 2023), <https://aimedalliance.org/wp-content/uploads/2023/07/SaveOnSP-Decision-Denying-Motion-to-Dismiss.pdf>. To date, the U.S. Department of Justice has not filed a statement of interest in the case.

¹⁵⁶ Johnson & Johnson, *Comments to Pennsylvania Department of Insurance Commonwealth Essential Health Benefits Benchmark Plan* (Sept. 1, 2023), https://www.insurance.pa.gov/Coverage/health-insurance/EHB-BenchmarkPlan/Documents/PublicComment_23/34_JJ_PA%20EHB%20Benchmark%20Comment_09012023.pdf.

¹⁵⁷ See *2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, Express Scripts, *supra* note 151.



certain medications must be classified as “essential” leaving the opportunity for the others to be classified as “non-essential health benefits.” Both essential and non-essential medications are important and necessary to a patient's health, but there are certain ACA rules that apply to only medications classified as essential.¹⁵⁸

We could find no publicly available data on how many people are subject to these “non-EHB” schemes. However, they are being perpetuated by some of the biggest insurers in the nation. Express Scripts, which claims to be the largest PBM and pharmacy in the U.S. serving more than 85 million people, has partnered with SaveOnSP.¹⁵⁹ The two promote their plan “to identify select drugs as non-essential health benefits, enabling maximum savings.”¹⁶⁰ Express Scripts is owned by health insurer Cigna, which pushes the SaveOnSP scheme in its employer plans, declaring high-cost drugs “non-EHB.”¹⁶¹

CVS Caremark, a PBM controlling 33% of the market, also uses “non-EHB” declarations to deprive plan enrollees of ACA cost sharing protections.¹⁶² Caremark promotes its PrudentRx Copay Program, including the following:

Because certain specialty medications do not qualify as “essential health benefits” (EHB) under the Affordable Care Act (ACA), member cost share payments for these medications, whether made by you or a manufacturer copayment assistance program, do not count towards the Plan's MOOP.¹⁶³

¹⁵⁸ Iona University, *SaveOnSP – Variable Copayments for Certain Specialty Pharmacy Medications*, <https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain>.

¹⁵⁹ About Express Scripts, <https://www.express-scripts.com/frontend/open-enrollment/networkhealthplan/about> (last visited Dec. 14, 2023).

¹⁶⁰ Express Scripts, *A richer specialty benefit with room to plan and grow*, <https://www.express-scripts.com/corporate/index.php/solutions/lowering-costs#saveonsp> (last visited Dec. 14, 2023).

¹⁶¹ Cigna, *Pay \$0 For Select Specialty Medications*, <https://hr.richmond.edu/benefits/insurance/medical-plans/pdf/SaveonSP.pdf>.

¹⁶² See *The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies*, Drug Channels (May 23, 2023), <https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html>.

¹⁶³ CVS Caremark, *The PrudentRx Copay Program Frequently Asked Questions*, https://www.caremark.com/portal/asset/TRS_PrudentRx_Member_FAQ.pdf (last visited Dec. 13, 2023). In a footnote, Caremark suggests that its definition of EHB is “authorized by the U.S. Department of Health and Human Services.”

Ohio's Niles City schools, which adopted the CVS PrudentRx plan, allows payment for non-EHB drugs to count toward the plan deductible when paid by a Health Savings Account (HSA), but will not count the payment toward the maximum out of pocket.¹⁶⁴ Although enrollment is "optional," PrudentRx notes that fewer than 1% of members opt out.¹⁶⁵

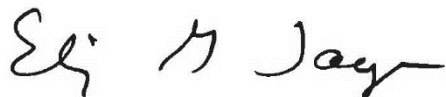
We strongly support the proposed § 156.122(f), which would codify the long-held policy that prescription drugs that exceed the minimum coverage requirements are EHB and subject to ACA cost sharing protections. We further call upon HHS to monitor compliance and end these unlawful and harmful schemes once and for all.

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,



Elizabeth G. Taylor
Executive Director

¹⁶⁴ CVS Health, *Frequently Asked Questions: The PrudentRx Solution Preserves Plan Design and Reduces Spend*, <https://www.nilescityschools.org/Downloads/External%20FAQ-%20PrudentRx.pdf> (last visited Dec. 14, 2023).

¹⁶⁵ *Id.*

