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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

Attn: RIN 0938–AV14
Request for Information; Essential Health Benefits

The National Health Law Program (NHeLP) protects and advances the health rights of low-income and underserved individuals, by advocating, educating, and litigating at the federal and state level. We appreciate the opportunity to comment on HHS' Request for Information (RFI) on Essential Health Benefits (EHB).

HHS has the statutory responsibility to periodically review and update EHB and, because the agency has not performed such a review and update since the Affordable Care Act (ACA) was enacted, we firmly believe this RFI is timely. Below we provide specific answers to some of HHS' questions, but we also take the opportunity to comment on the need to establish a standardized process to review and update EHBs in the future and on the need for HHS to adopt stronger standards for each EHB category at the federal level. Many of our comments reiterate previous points we have raised in letters submitted to the Center for Consumer Information and Insurance Oversight (CCIIO) and in conversations with the agency.[1] These changes are essential to ensure that access to essential services is

improved and remaining gaps in coverage are addressed in a way that reduces health disparities and the health status of private health plan consumers.

I. Benefit Description in EHB-Benchmark Plan Documents

Question: We seek public comment on the understanding that States are effective in enforcing EHB requirements and ensuring that benefits are still treated as EHB when the EHB BBP is ambiguous or lacks detail, including to what extent States may require additional guidance on how to ensure that plans are interpreting the EHB-benchmark plan documents in a manner that provides EHB coverage to consumers, consistent with applicable requirements.

General Comments Regarding Effectiveness of States as Enforcers of EHB

HHS asserts in the RFI that "based on our discussions with States and a lack of consumer complaints about exclusions or claims denials, plans subject to EHB requirements do not appear to be excluding services that are generally understood to be covered, regardless of their specific inclusion in the relevant EHB-benchmark plan document. Accordingly, we believe that the states have generally proven to be effective enforcers of the EHB requirement in ensuring that benefits are still treated as EHB in instances where the EHB-benchmark plan language is ambiguous or lacking in detail."

We strongly disagree with this statement. In particular, we take issue with the assessment that a lack of consumer complaints about exclusions or claims denials is indicative of the effectiveness of states in ensuring that benefits are covered as EHBs when the benchmark plan is ambiguous. Health consumers may not have access to all necessary information

[1] 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/ [hereinafter *NHeLP Letter Re: Advancing Health Equity Trough EHB*]; 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/ [hereinafter *NHeLP Letter Re: Rx and Maternity Care EHB Standards*].

regarding their health care coverage and cost associated with these services.[2] In the same way that benchmark plan documents tend to be ambiguous regarding coverage, Qualified Health Plan (QHP) documents are likely to lack detailed information about services covered within each EHB category. As a result, consumers may not know about exclusions of coverage until a service request gets denied.

While it is true that consumers may file complaints after a service is denied by a plan, the reality is that most health consumers do not have the time, resources, and information needed to proceed with these types of complaints. Even if these barriers are overcome and consumers know about federal EHB coverage requirements, just like HHS, consumers may very well assume that states are properly enforcing these requirements and that the coverage exclusion and denial was proper. This outcome is compounded by the lack of standardization of EHB definitions at the federal level. Because only a couple of EHB categories have been partially defined, consumers are unlikely to know specifically which services their QHPs are required to cover. Reliance on ambiguous benchmark plans, rather than facilitating state enforcement of coverage and provision of EHBs, makes it more difficult for consumers to understand coverage requirements and seek recourse when a service is denied. In other words, there are few complaints about EHB coverage denials precisely because benchmark plans are ambiguous and consumers lack clarity regarding coverage requirements, not because states are properly enforcing coverage requirements when a benchmark plan is ambiguous.

There are certainly ways to improve state enforcement and oversight of EHB coverage, and we outline some of those below. However, we would be remiss if we fail to call out the elephant in the room: **all of the problems with lack of clarity and enforcement of EHB coverage relate to HHS' decision to defer its authority to define EHB to the states and all of the solutions to that problem require increased involvement from HHS in the oversight and enforcement process**.

As we have repeatedly said in commenting opportunities since 2011, the benchmarking process creates widely varying coverage from state to state, as services offered in many existing health plans (including mandated services) vary depending on the types of employers in that state and the health of the individuals served. Vague federal standards, as is currently the norm, lead to different benefits packages, confused consumers, confused payors,

[2] Willa Hart, *Lack of price transparency still keeping many from seeking health care* (May 31, 2022), https://www.benefitspro.com/2022/05/31/lack-of-price-transparency-still-keeping-many-from-seeking-health-care/.

inefficient and unaccounted for use of public funds, and significant administrative costs. The approach also undermines the basic reform objectives of the ACA: developing a simple and navigable insurance market for consumers, promoting health care systems that are unified as opposed to siloed, and ensuring widespread and comprehensive access to coverage for low-income and vulnerable populations.

To be clear, while we oppose HHS delegating its authority to define EHB to states in principle, we do not believe eliminating the benchmark approach in its entirety is the only solution to improving EHB coverage. We believe it is still possible for states to play an important role in defining benefits while HHS moves toward standardizing a minimum set of benefits and enforcement of such coverage requirements at the federal level. In other words, HHS could allow states to define EHB categories, as long as those definitions satisfy minimum coverage requirements established by HHS for each benefit category. That approach would allow states to modify EHB coverage beyond a minimum standard definition, but would protect individuals in states that are prone to reducing benefits while prioritizing cost containment by creating a national floor of benefits.

Establishing a federal floor would also significantly improve issues that arise out of ambiguity of benchmark plans because, at least for the most basic services, consumers would not have to deal with varying EHB standards across all states. Consumers would be significantly more likely to understand that coverage of certain basic services within each EHB category is protected by federal law irrespective of what the state benchmark plan covers. Similarly, consumers would not have to rely on inconsistent enforcement that depends entirely on their state of residence.

Specific Recommendations to Improve Enforcement of EHB Coverage Requirements and Other Federal Requirements

HHS must create a transparent and inclusive standardized process for states to report EHB benchmark plan coverage. While we appreciate that HHS has posted supporting plan documents for the final 2017 EHB benchmark plans, many times these documents refer to additional documents for coverage details, e.g., durable medical equipment (DME) formularies, benefits schedules, or appendices which are not included with the plan documents, but are needed in order to figure out what benefits are covered by the plan.

Evidence of coverage and certificate of coverage documents generally are confusing or incomplete, and many times these documents include multiple amendments which make it difficult to determine covered benefits. The level of detail in the benefits and limits charts provided for each state along with the plan documents varies significantly from state to state, with most states simply indicating whether a benefit is covered. The charts should be amended to provide an accurate picture of covered benefits and, thus, include specificity about covered benefits and limits. This way everyone will understand exactly what benefits are included in the BBP and how they are covered. Also, with more detail, the charts could even become a helpful tool for state regulators to ensure coverage of EHBs by health plans and issuers. For instance, we urge HHS to require states to classify each benefit by EHB category as doing so would provide an additional tool to evaluate whether the state is requiring substantial coverage within each category and whether additional categories are being covered.

We recommend that HHS require states/issuers to include plan documents and any referenced documents that provide coverage details for the state's benchmark plan, and that all of those documents (including formularies and appendices), not just summaries and evidence of coverage, get posted on the CCIIO website.

In addition, HHS should provide states with guidance regarding their ability to add coverage requirements or adjust their benchmark plans in order to ensure compliance with federal requirements without running afoul of defrayal requirements or the generosity limit. We know of various states that have considered enacting legislation to mandate coverage of certain benefits because they believe plans are violating federal law.[3] Specifically, we believe states are being deterred from enacting policies to ensure compliance with the federal Mental Health

[3] For example, Vermont considered enacting a mandate requiring coverage of hearing aids, but ultimately only applied the mandate to non-EHB plans. Though Vermont's new law still requires the Department of Financial Regulation to adopt a new mandate through the benchmarking process, that addition would still be constrained by the generosity limit and would not take effect until at least 2024. 2022 Vt. Acts & Resolves 108. https://legislature.vermont.gov/bill/status/2022/H.266. The State of Washington also enacted a new law clarifying that coverage of emergency services extends to behavioral health emergency services. 2022 Wash. Sess. Laws 263. https://app.leg.wa.gov/billsummary?billnumber=1688&year=2022#documentSection. That law, however, hinges on a memorandum from the Washington Office of the Insurance Commissioner explaining that not covering behavioral health emergency services, or excluding some types of emergency services for behavioral health, such as mobile crisis services, would constitute a violation of MHPAEA. WA Off. Ins. Comm'r, Memorandum from Jane Beyer, Senior Health Policy Advisor Re: Behavioral Health Emergency Services Under E2SHB 1688 (Chap. 263, Laws od 2022), https://www.insurance.wa.gov/sites/default/files/documents/e2shb-1688-mhpaea-memo.pdf.

Parity and Addiction Equity Act (MHPAEA) and with federal non-discrimination provision (including both Section 1557 and EHB non-discrimination provisions) because of concerns related to increased cost to the state. For example, in an effort to counter benefit design discrimination against individuals with disabilities, some states have considered adding requirements around DME and hearing aids but have either refrained from doing so when faced with defrayal concerns or have added a clause making the law ineffective if HHS requires defrayal.[4]

Given the urgency to protect consumers against parity and non-discrimination violations, we urge HHS to provide guidance to states clarifying that, when a state passes a mandate (whether through legislation, regulation, or other state action) for purposes of ensuring that health plans comply with parity or non-discrimination rules, the state would not have to defray the cost of such a mandate. This would allow states to freely and more strongly enforce federal rules that already apply to private plans, but that states are ineffective in enforcing in part because of limitations on new mandates at the federal level.

Similarly, while HHS has said that a state will not have to defray the cost of new mandated benefits when added through the benchmarking process, proposed benchmark plans must not be more generous than the most generous benchmark plan option the state had in 2017. This means that a state seeking to add a benefit to ensure compliance with parity or non-discrimination would not be able to add other necessary benefits if, in the aggregate, all the additions result in the proposed plan exceeding the generosity limit. We believe that result is counter to what the ACA intended. To correct this unintended consequence, **HHS should clarify that when a new benefit is added through the benchmarking process in order to ensure compliance with federal requirements, that change would not be counted towards the generosity limit in the actuarial analysis.** This would not only provide additional tools for states to enforce parity and non-discrimination, but would also enhance states' ability to address unmet health needs and address health disparities by adding other benefits where gaps currently exist.

We also believe HHS should address, through guidance, the need for states to update their benchmark plans to ensure they comply with parity requirements. The insurance plans

[4] *See, e.g.,* CA AB 598 (2019) (seeking to require health plans to cover hearing aids for minors) and VT S.320 (2020) (seeking to require health plans to cover hearing aids for all enrollees). Both of these bills failed passage after advocates raised concerns of the possibility of defrayal.

selected to serve as the states' 2017 benchmark plans (the benchmark plans still in effect in many states) were not subject to MHPAEA requirements at the time. While parity compliance cannot be fully determined from a review of plan documents, a review of 2017 benchmark plan options found several facial and likely parity violations.[5] As a result, although plans modeled on those benchmark plans must comply with parity, plans sold to consumers in these states are more likely to violate parity.[6] In response to this lack of compliance with parity, HHS should issue guidance urging states to review their benchmark plans for compliance with parity and provide examples of what states should consider when making this determination. **HHS should urge states that find their benchmark plans do not comply with parity to use one of the three current benchmark options to update the plans for compliance with parity. Finally, the guidance should inform states that any proposed benchmark plan that HHS deems to be out-of-compliance with parity will be rejected by the agency.**

II. Typical Employer Plans

Question: We seek comments on changes in the scope of benefits offered by employer plans since PY 2014. In particular, we seek comments on the generosity of the current typical employer plans as described at § 156.100(a)(1) through (4) and § 156.111(b)(2)(i)(B), and whether they are reflective of the scope of benefits provided under employer plans in more recent years.

Legal Analysis of The ACA's Typical Employer Plan Provision

HHS seeks comments regarding the scope of benefits offered by employer plans since 2014 in order to determine typicality of employer plan coverage for purposes of defining EHB pursuant to 42 U.S.C. § 18022(b). We take this opportunity to caution HHS that interpreting the typical employer plan provision (hereinafter "TEP provision") as a hard cap on EHB coverage would

[5] P'ship to End Addiction, *Uncovering Coverage Gaps: A Review of Addiction Benefits in ACA Plans* (June 2016), https://drugfree.org/reports/uncovering-coverage-gaps-a-review-of-addiction-benefits-in-aca-plans/.

[6] For example, Mississippi offered a plan in 2017 that explicitly covered partial hospitalization for mental health but excluded coverage for partial hospitalization for SUD while offering coverage for home health care services; plans offered in Michigan, Montana, New Hampshire and D.C. in 2017 imposed treatment standards for SUD services that did not exist for medical/surgical services; Vermont offered a plan in 2017 that contained an ongoing concurrent review requirement for SUD services that did not appear to exist for medical services; and fourteen states offered plans in 2017 that covered methadone for the treatment of pain but excluded coverage of methadone for opioid use disorder. *Id.*

create or maintain significant gaps in Marketplace coverage, hampering HHS' authority under the ACA to periodically review and update EHB. **We urge HHS not to set maximum coverage standards using the information about typical employer plan coverage obtained through the RFI and other potential surveys (including surveys from the Department of Labor as contemplated by the statute), and instead use typicality as a guide for minimum coverage levels, just as it has done since the inception of the benchmarking process.**

The ACA gave the HHS Secretary broad authority to define EHB coverage, except that EHB coverage must always extend to at least the ten EHB categories listed in the statute.[7] Furthermore, the HHS Secretary has the authority and responsibility to periodically review and update EHB coverage when such review shows that updates are necessary to account for changes in medical evidence or scientific advancement or to close remaining gaps in coverage.[8] The Secretary's statutory authority to define, review, and update EHB is subject to the TEP provision, which states that "the Secretary shall ensure that the scope of [EHB]…is equal to the scope of benefits provided under a typical employer plan."[9] The Secretary has considerable discretion in considering the impact of the ACA's TEP Provision on EHBs, and we support the Secretary exercising this discretion when updating EHBs. The exercise of discretion is crucially important because the benefit generosity under employer plans has decreased as these plans have become less affordable and more burdensome upon Americans.

We are concerned that HHS may seek to interpret the "*equal to*" phrase as requiring EHB coverage that does not exceed the coverage typically provided by employer-based plans. This interpretation is problematic because employer plans have traditionally excluded the very same services the ACA meant to improve access to, including mental health and substance use disorder (SUD) services, maternity and newborn care, and rehabilitative and habilitative

[7] 42 U.S.C. § 18022(b)(1).
[8] 42 U.S.C. § 18022(b)(4)(G)–(H).
[9] 42 U.S.C. § 18022(b)(2)(A). The ACA states that what constitutes a typical employer plan is to be determined by the HHS Secretary and informed by a survey of employer-based plans conducted by the Department of Labor. *Id.* From the outset, we note that only once since the enactment of the ACA, in 2011, has DOL conducted an employer plan survey. The report from that survey is now over ten years old and the information it contains is likely outdated. While we appreciate HHS seeking information from stakeholders, we believe HHS needs to ask DOL for an updated survey and report and that the information obtained through this RFI is insufficient to make a determination about what constitutes typical employer coverage.

services.[10] As HHS has acknowledged, since many employer plans offer skimpy benefits for many of the EHB categories, strictly applying the TEP equivalence provision may inadvertently end up dragging down coverage of EHBs to the point of making the EHB mandate meaningless. It would make no sense for the ACA to create a requirement to cover a specific service and apply a hard cap based on typical employer plan coverage when that coverage is nearly nonexistent.

In addition, the purpose of the EHB provision is to increase access to key services and close gaps that persisted prior to the enactment of the ACA. The shortcomings in many employer plans prompted Congress to include EHB as a key component of the ACA. Congress sought to invest in these services beyond pre-ACA minimum norms. Notably, prior to the ACA, 75 percent of non-group market plans did not cover maternity care (delivery/inpatient care), and 45 percent did not cover inpatient/outpatient SUD services.[11] Under the harmonious-reading canon of statutory construction, a section requiring EHB benefits to be "equal to" a typical employer plan arguably should not be construed as "strictly no more than," because a reading establishing a ceiling would make it contradictory to other provisions in the ACA seeking improvements in coverage of EHBs.

Applying typical employer plan coverage as a hard cap is also contrary to the statute conferring HHS the authority to periodically review and update EHBs, particularly when new coverage requirements are necessary to account for changes in medical evidence and scientific advancement. If changes in medical evidence indicate that a particular and relatively new service should be made available for beneficiaries, it likely will take some time for most employer plans to extend coverage to those services. The ACA provision allowing HHS to review and update EHB coverage clearly did not intend for beneficiaries in the Marketplace to be at the mercy of employer plans deciding when to cover new and effective services and procedures, especially given the history of employer plans excluding necessary services.

In addition, applying typical employer plan coverage as a hard cap would make the authority to review and update EHB meaningless. If Congress had intended EHB updates to be strictly limited by typical employer plan coverage, it would not have expressly authorized HHS to

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[10] ASPE, *Essential Health Benefits: Individual Market Coverage* (Dec. 16, 2011), https://aspe.hhs.gov/sites/default/files/private/pdf/76356/ib.pdf.

[11] Gary Claxton et al., Kaiser Fam. Found., *Would States Eliminate Key Benefits if AHCA Waivers are Enacted?*, Kaiser Family Foundation (June 14, 2017), https://www.kff.org/health-reform/issue-brief/would-states-eliminate-key-benefits-if-ahca-waivers-are-enacted/.

review EHB and would not have provided clear bases for adding new benefits: changes in medical evidence and scientific advancement and remaining gaps in coverage. If Congress intended the typical employer plan provision to be read as a hard cap on benefits, HHS would only need to review typical employer plan coverage when updating, irrespective of scientific advancement and gaps in coverage. Clearly, that is not what Congress did.

HHS has both implicitly and explicitly recognized that typical employer coverage should not be treated as a hard cap on EHB coverage on several instances when establishing or modifying the benchmarking process. For example, while neither the ACA nor HHS explicitly define a typical employer plan, in determining the scope of EHB during early implementation of the requirement, the 2011 DOL report informed the subsequently adopted benchmark approach and the report's findings served as a floor for EHB coverage in the individual and small group market.[12] As a result, most of the base-benchmark plan options generally provide a scope of EHB coverage that is equal to, or exceeds the coverage typically provided in employer plans, as described in the DOL report.

HHS was even more explicit regarding typicality when adopting the current standard for the EHB benchmarking process. The current standard allows states to add new service requirements to their benchmark plans as long as the proposed plan does not exceed the generosity of the most generous benchmark option in 2018.[13] On the opposite end, the rules specify that a proposed plan should be at least as comprehensive as a typical employer plan in the state.[14] Consistent with the ACA, HHS did not set TEP as the ceiling; rather, the rule

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[12] CCIIO, Essential Health Benefits Bulletin (Dec. 16, 2011), https://www.cms.gov/cciio/resources/files/downloads/essential_health_benefits_bulletin.pdf.
[13] 45 C.F.R. § 156.111(b)(2)(ii).
[14] 45 C.F.R. § 156.111(b)(2)(i). While we strongly support HHS' decision to establish typical employer plan coverage as a floor and believe the same logic should apply when considering typicality for the purpose of defining, reviewing, and updating EHB at the federal level, we nonetheless continue to disagree with HHS' current definition of typical employer plans for purposes of the state benchmarking process. As we said in comments submitted in response to the proposed Notice of Benefit and Payment Parameters for 2019, that typical employer plan definition completely ignores the 2011 DOL report and the whole concept of "typicality." The definition merely provides that a typical employer plan is one whose enrollment exceeds 5,000 enrollees in one or more states, but is silent as to the scope of coverage typically seen in employer-based plans. In other words, the definition bases typicality on enrollment in a single plan instead of comparability of benefits across multiple employer plans. We strongly believe that a definition of typical employer plan must be informed by the DOL report on medical benefits typically covered by employers, which are measured by analyzing coverage across multiple employers. By defining a typical employer plan based solely on enrollment, the proposed

specifies that typicality serves as a floor with states being required to submit an actuarial analysis certifying that the proposed benchmark "provide[s] a scope of benefits ***equal to, or greater than***, [...] the scope of benefits provided under a typical employer plan."[15] The actuarial certifications completed under the state benchmark system therefore treat the scope of a state's "typical employer plan" as a *lower limit* for actuarial certification, and treat the scope of a "most generous plan" as an upper limit.[16] While these principles have only been applied at the state level, they should similarly be applied to any future actuarial certification of EHB at the federal level.[17]

In relevant part, the purpose and intent of the ACA is two-fold. First, while the ACA did not provide further clarity around the TEP Provision, the legislature clearly intended EHB plan design to be flexible. Both House and Senate legislative reports expressed Congress' intent to allow flexibility in EHB plan design.[18] Interpreting the TEP Provision as establishing a benefit ceiling would contravene the legislative intent of flexibility. Second, the ACA, and its EHB provisions, were passed to *increase* coverage and to *reduce* the burden of healthcare costs on the population.[19]

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approach contravenes the ACA's requirement that the scope of EHB in the Marketplace be equal to the scope of "benefits typically covered by employers."

[15] *Id.* (emphasis added).

[16] *See Id.*; *see also* 83 Fed. Reg. at 17011 ("[T]he requirement that a State's EHB-benchmark plan provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, as defined at § 156.111(b)(2), establishes a *minimum scope of benefits*. Furthermore, the requirement that the EHB-benchmark plan cannot exceed the generosity of the most generous among a set of comparison plans, which are those group market plans that comprise the basis for the scope of benefits under the current definition of EHB, further limits the range of benefits that can be considered EHB. Together with the other requirements specified at § 156.111(b)(2), *these requirements provide States with flexibility to adjust their States' EHB-benchmark plan within a limited range*") (emphasis added).

[17] For an example of actuarial comparison of relative benefit values of state-level plans, see State of South Dakota, *Essential Health Benefits, Analysis of 2021 Benchmark Plan Options* (June 2019), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/actuarial%20report%20and%20certificate_sd.pdf.

[18] *See* H.R. Rep. No. 111-299, Part 1, at 378–380 (describing an essential benefits "package" and actuarial analysis of the EHB package benefit generosity as a "summary measure" providing benefit flexibility: "Because these are summary measures, two plans that are actuarially equivalent may not provide the same benefits for any two individuals."); *see also* S. Rept. No. 111-89 at 32 ("[s]ome flexibility in plan design would be allowed as long as it did not encourage adverse selection.").

[19] *See* S. Rept. No. 111-89 at 4 ("[T]his legislation achieves the goals of expanding health care coverage to the uninsured, reducing health care costs and improving the quality of care by transforming

Moreover, the ACA requires the Secretary "address any gaps in access to coverage or changes in the evidence base" when updating EHBs.[20] This language would be superfluous if, notwithstanding coverage gaps, the Secretary had to cap EHB benefits to match the TEP. Rather, the requirements to review and update EHBs further demonstrates that Congress did not intend the TEP Provision to be strictly construed when updating EHBs, but instead intended the Secretary to have the flexibility to address coverage gaps. The need for this reading becomes even more important when considering the gaps in coverage that remain today in areas such as maternity and newborn care, mental health and substance use disorder services, and rehabilitative and habilitative services and devices. In enacting the ACA, Congress intended the Secretary to have enough flexibility to respond to these and other coverage gaps and changes in medical evidence by updating EHBs accordingly.

Generosity of Employer Plans Since 2014

There is little data available regarding how employer plan coverage has changed since 2014. For that reason, we reiterate that HHS has the responsibility to work with DOL to analyze the current landscape of employer plans and the services they typically offer and use the results from such a survey to determine minimum coverage requirements in different EHB categories.

While aggregate data on services is lacking, vast evidence does demonstrate that employer plans have become less generous since 2014. For instance, workers are facing ever-rising premiums for employer plans. The average premium for employer-sponsored family coverage has increased 20 percent over the last five years and 43 percent over the last ten years—

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the health care delivery system"); s*ee also* Administration of Barack H. Obama, 2010, Remarks on Signing the Patient Protection and Affordable Care Act (March 23, 2010) ("Once this reform is implemented, health insurance exchanges will be created, a competitive marketplace where uninsured people and small businesses will finally be able to purchase affordable, quality insurance. . . And we have now just enshrined, as soon as I sign this bill, the core principle that everybody should have some basic security when it comes to their health care.").

[20] 42 U.S.C. § 18022(b)(4)(H).

outpacing both inflation and wage growth.[21] This trend is only expected to continue, with surveys predicting even larger premium hikes in the coming years.[22]

People in employer plans are also subject to rising out-of-pocket costs. Employer plans are increasingly requiring enrollees to pay a deductible, and the average deductible is also climbing.[23] In the past five years, the percentage of covered employees with a deductible of $2,000 or more has increased from 22 percent to 32 percent.[24]

Moreover, a 2019 study found that after the ACA's passage, the greatest growth in underinsured Americans has occurred among those with employer-based coverage—a 40 percent increase from 2014 to 2018.[25] Employees now pay a higher share of premium costs and face higher coinsurance, copayments, and deductibles than a decade ago.[26] The share of adults subscribed to health plans without deductibles has also plummeted, from 40 percent in 2003 to 22 percent in 2016, while at the same time average deductibles have doubled in size.[27] The discretion granted the Secretary must ensure that this troubling trajectory will not constrain future EHB updates.

As employer plans grow more expensive, more enrollees struggle to afford care. Four in ten individuals with employer coverage report difficulty affording medical care, prescriptions, or premiums, and about half report they have skipped or delayed needed care due to costs.[28]

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[21] Liz Hamel et al., Kaiser Family Found., *Employer Health Benefits: 2022 Annual Survey* (2022), https://files.kff.org/attachment/Report-Employer-Health-Benefits-2022-Annual-Survey.pdf.
[22] Willis Towers Watkins, *U.S. employers double down on controlling healthcare costs*, enhancing affordability (Sept. 15, 2022), https://www.wtwco.com/en-US/News/2022/09/us-employers-double-down-on-controlling-healthcare-costs-enhancing-affordability.
[23] Hamel et al., *supra* note 21, at 10.
[24] *Id.* at 11.
[25] Sara R. Collins, Herman K. Bhupal, & Michelle M. Doty, The Commonwealth Fund, *Health Insurance Coverage Eight Years After the ACA: Fewer Uninsured Americans and Shorter Coverage Gaps, But More Underinsured* (Feb. 2019), https://www.commonwealthfund.org/publications/issue-briefs/2019/feb/health-insurance-coverage-eight-years-after-aca.
[26] Nat'l Acad. of Sci., *Changing Patterns of Health Insurance and Health-Care Delivery* (March 2018).
[27] Sara R. Collins et al., The Commonwealth Fund, *The Slowdown in Employer Insurance Cost Growth: Why Many Workers Still Feel the Pinch* (Oct. 2016), https://www.commonwealthfund.org/publications/issue-briefs/2016/oct/slowdown-employer-insurance-cost-growth-why-many-workers-still.
[28] Liz Hamel et al., Kaiser Fam. Found., *Kaiser Family Foundation / LA Times Survey Of Adults With Employer-Sponsored Health Insurance* (2019), https://files.kff.org/attachment/Report-KFF-LA-Times-Survey-of-Adults-with-Employer-Sponsored-Health-Insurance.

These effects are also distributed unequally; low-income individuals and people with chronic conditions are both more likely to report difficulty affording care or delaying necessary treatment.[29] A recent study also found that women in employer plans were more likely than men to be unable to pay for needed health care services.[30] Another study found steady increases in out-of-pocket spending for maternity care among women with employer-sponsored insurance.[31] Such price increases can lead to adverse health effects when people skip or delay necessary care. For example, one recent study found that people with diabetes whose employers switched to a high-deductible health plan were "significantly more likely to experience serious, but preventable, acute diabetes complications."[32]

In short, employer plans—once considered the "gold standard" of insurance coverage—are growing increasingly inadequate and leaving workers underinsured. This inadequacy is completely at odds with the purpose of the ACA. Constricting the scope of EHBs because employer plans have done the same would run directly counter to the ACA's statutory intent as it would *increase* the burden of healthcare costs. The ACA should not be construed to produce absurd results.[33]

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[29] *Id.* at 13–18.

[30] Anvi Gupta & José A. Pagán, *Trends in Reported Health Care Affordability for Men and Women with Employer-Sponsored Health Insurance Coverage in the US, 2000 to 2020*, 328 J. AM. MED. ASS'N 2448 (2022). Throughout the comments, we occasionally use the words "woman" or "women." This is not intended to be exclusionary. We recognize that different categories of people, including cisgender women and transgender men, are able to become pregnant. Accordingly, we have tried to limit the use of "woman" or "women" to conform to statutory and regulatory language, cited research and data, or quoted statements and material. Our underlying goal is to share findings and data to help ongoing efforts to ensure that all pregnant and postpartum people, regardless of gender, gender identity, and gender expression, have access to full spectrum doula care.

[31] Michelle H. Moniz, *Out-Of-Pocket Spending for Maternity Care Among Women with Employer-Based Insurance*, 2008–15, 39 HEALTH AFF. 18 (2020).

[32] David H. Jiang et al., *Evaluation of High-Deductible Health Plans and Acute Glycemic Complications Among Adults With Diabetes*, 6 JAMA Network Open 1 (2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800697.

[33] *See, e.g.*, *United States v. Granderson,* 511 U.S. 39, 47 n.5 (1994); *Public Citizen v. Department of Justice,* 491 U.S. 440, 454 (1989).

III. Review of EHB

A. Barriers of Accessing Services Due to Coverage or Cost

Question: We seek comment on whether and to what extent consumers enrolled in plans that provide EHB are facing any difficulty accessing needed services due to coverage or cost.

- *Are there significant barriers for consumers to access mental health and substance use disorder services, including behavioral health services that are EHB? To what extent has the utilization of telehealth impacted access to the behavioral health services that are EHB, particularly during the COVID–19 pandemic? How could telehealth utilization better address potential gaps in consumer access to EHB for behavioral health services or other health care services?*

Barriers to Accessing Mental Health and Substance Use Disorder (MH/SUD) Services

As noted in our earlier letter to HHS, many EHB plans that do cover a comprehensive set of behavioral health services still circumvent MH/SUD coverage requirements by imposing strict medical necessity criteria that are incompatible with generally accepted standards of care and which create barriers to accessing services. For example, plans may limit covered MH/SUD services to a specific subset of MH/SUD diagnoses or may require a level of need that exceeds the need required under most accepted MH/SUD standards of care.[34] Courts have begun holding plans accountable for utilization of overly restrictive MH/SUD medical necessity criteria. For example, in *Wit, et al, v. United Behavioral Health (UBH)*, a U.S. district court held that UBH violated its ERISA fiduciary duties by using MH/SUD medical necessity criteria that were significantly more restrictive than generally accepted criteria.[35] However, enrollees should not have to rely on litigation to access health care. Instead, to close this loophole, HHS should specify that plans should align medical necessity criteria to conform to generally accepted standards of care.

[34] See Nat'l Health Law Prog., *Wit v. United Behavioral Health*, Brief amicus curiae of Nat'l Health Law Prog., et al. (May 26, 2021), https://healthlaw.org/resource/wit-v-united-behavioral-health-care-u-s-court-of-appeals-ninth-circuit/.
[35] *Wit v. United Behavioral Health*, 317 F.R.D. 106 (N.D. Cal. 2016).

In addition, plans often impose utilization control tools on MH/SUD services that effectively act as barriers to necessary and frequently life-saving services. For example, while health plans routinely use prior authorization, these requirements impose a unique barrier on individuals seeking MH/SUD treatment because they delay the initiation of care at the critical moment a patient urgently needs treatment. This delay can lead to serious consequences for patients, including failing to return for subsequent appointments, stopping the use of medications, resuming substance use, medical complications, overdose and death. In addition to prior authorization, many plans still impose step therapy, quantity limits, and concurrent counseling requirements on key behavioral health services, such as medication assisted treatment (MAT). These limitations help contain cost, but only at the expense of timely access to medically necessary services. **We believe HHS should prohibit the use of prior authorization for MH/SUD benefits under its authority to define EHB and urge states to remove all other utilization controls for MH/SUD through the benchmarking process while emphasizing that such policies would not count against the generosity limit when done to comply with parity.**

Plans also use narrow provider networks to reduce costs and utilization of services. Although the ACA requires QHPs to maintain adequate provider networks, many plans have closed or narrow networks, which forces enrollees to seek much more expensive services out of network or go without treatment altogether.[36] This is particularly problematic given that many MH/SUD providers do not participate in insurance plans. Federal regulations require ACA plans to publish up-to-date and accurate provider directories that are publicly available.[37] However, CMS' implementation and oversight of network adequacy standards and provider director accuracy has been insufficient to compel plan compliance with these requirements.[38] **HHS must require plans to have a sufficient number of community-based providers to ensure appropriate care in the coverage area, better define network adequacy standards, and enforce requirements for plans to maintain adequate networks and accurate provider directories.**

[36] Karen Pollitz, Kaiser Fam. Found., *Network Adequacy Standards and Enforcement* (Feb. 4, 2022), https://www.kff.org/health-reform/issue-brief/network-adequacy-standards-and-enforcement/.
[37] 42 C.F.R. § 156.230(a).
[38] Pollitz, *supra* note 36.

Utilization of Telehealth in General

The COVID-19 pandemic has greatly spurred telehealth utilization in the United States and across the globe, particularly for behavioral health services.[39] Telehealth has been used to continue and expand access to care by expanding the pool of providers, and in some cases, improving quality of care, offering unique benefits for people with certain diagnoses like social anxiety, obsessive-compulsive disorders, and SUDs.[40]

Providers have reported that telehealth offers them the ability to better understand patients in their everyday surroundings during a convenient time for the patients; they assert that telehealth reduces stigma associated with attending services in-person at a behavioral health facility.[41] Most of them also reported a reduction in no-show rates coinciding with the increased use of telebehavioral health.[42] Providers appreciated the convenience that telehealth also

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[39] *See* Am. Health Ins. Plans, *Health Insurance Providers Facilitate Broad Access to Mental Health Support: Key Results of Industry Survey on Behavioral Health Care* (Aug. 2022), https://ahiporg-production.s3.amazonaws.com/documents/Mental-Health-Survey-July-2022-FINAL.pdf (finding that 100 percent of health plans offered coverage for behavioral health services provided via telehealth. Additionally, commercial health plans have increased their number of in-network behavioral health services by an average of 48 percent over the last three years. About 89 percent of health plans said they were recruiting more behavioral health care providers, including 83 percent who said they were looking to recruit a more diverse group of providers).

[40] Nat'l Council for Mental Wellbeing, *Innovations in Telehealth in Mental Health and Substance Use During Covid-19* 3 (July 2022), https://www.thenationalcouncil.org/wp-content/uploads/2022/07/11.07.22_Innovations-In-Telebehavioral-Health-Paper_V5.pdf [hereinafter *Innovations in Telehealth in Mental Health and Substance Use During Covid-19*]. *See also* Laurie E. Steffen et al., *Efficacy of a Telehealth Intervention on Colonoscopy Uptake when Cost is a Barrier: The Family CARE Cluster Randomized Controlled Trial*, 24 CANCER EPIDEMIOLOGY BIOMARKERS PREV. 8, 1311–1318 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4734378/.

[41] Steffen et al., *supra* note 40.

[42] *Id.* at 7. *See also* Anuja Vaidya, *53% of Healthcare Providers Say Adding Telehealth Drove Up Patient Visits* (July 12, 2022), https://mhealthintelligence.com/news/53-of-healthcare-providers-say-adding-telehealth-drove-up-patient-visits?eid=CXTEL000000649894&elqCampaignId=26552&utm_source=nl&utm_medium=email&utm_campaign=newsletter&elqTrackId=36fa35a9448b4b538a9d84d5b530ea73&elq=c94c067617f04b2cb66913b1c85f592f&elqaid=27396&elqat=1&elqCampaignId=26552 (citing a study released by CVS Health confirming that the addition of telehealth options led to an increase in patient visits. Seventy percent of surveyed health care consumers believe a telehealth appointment for behavioral health services would be more convenient for them, fifty-five percent also said that the availability of telebehavioral visits would increase the likelihood of them seeking this type of care, and fifty-seven percent thought a virtual visit would be more private than an in-person visit).

affords for them and its ability to save costs compared to in-person care since it reduces overhead costs.[43] The American Psychiatric Association has found that telebehavioral therapy has led to better client outcomes by helping to facilitate integration of behavioral health and primary care as well as by reducing unnecessary visits to the emergency room.[44] Finally, the National Council on Mental Well-Being (NCMW) concluded that offering telehealth services to patients allows patients to access treatment and establish clinical relationships for the first time; it is not simply a temporary substitute for in-person care.[45] For some people, NCMW stated, telehealth is the only option because of socio-economic factors, convenience, or preference.[46]

While the United States continues to be in a public health emergency and will have to reevaluate how the permanent use of telehealth will take place, telehealth utilization is here to stay. Research, however, has been inconsistent in terms of showing how disparities exist across race, gender, income level, disability, etc. On one hand, data indicates that Black, Latinx, Indigenous, and Asians are less likely to have a telemedicine visit compared to their white counterparts.[47] Similarly, people younger than eighteen years of age and older adults are less likely to have a telemedicine visit than non-elderly adults.[48] Rural residents have also been found less likely to use telemedicine than metropolitan residents.[49]

On the other hand, various studies report that ethnic minorities and other underserved populations are taking advantage of telehealth services, and often at higher rates. For example, a study on the largest employer insurance plans in California found that telehealth utilization was highest among patients located in zip codes that were lower income, had more

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[43] Steffen et al., *supra* note 40, at 7.
[44] *Id.* at 7 (citing Am. Psychiatric Ass'n. What is Telepsychiatry, https://www.psychiatry.org/patients-families/telepsychiatry (last visited Jan. 20, 2023).
[45] *See Innovations in Telehealth in Mental Health and Substance Use During Covid-19*, *supra* note 40.
[46] *Id.*
[47] *See e.g.*, Omolola E. Adepoju, *Utilization Gaps During the COVID-19 Pandemic: Racial and Ethnic Disparities in Telemedicine Uptake in Federally Qualified Health Center Clinics*, 37 J. Gen. Internal Med. 1191 (2022), https://link.springer.com/article/10.1007/s11606-021-07304-4?utm_source=STAT%20Newsletters&utm_campaign=90e06dac7e-health_tech_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-90e06dac7e-154020534; Jeongyoung Park et al., *Are State Telehealth Policies Associated With The Use Of Telehealth Services Among Underserved Populations?* 37 HEALTH AFF. 12 (Dec. 2018), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05101.
[48] Adepoju, *supra* note 47.
[49] *Id.*

non-white residents, and had more non-English speakers.[50] Similarly, a study of roughly thirty million Medicare fee-for-service claims revealed that beneficiaries in disadvantaged neighborhoods increased telemedicine use during the COVID-19 pandemic.[51]

Analyzing this research in the aggregate, underserved populations fared better in their telehealth use *when coverage was accompanied by other changes* like broadband and digital equipment access, health plans covered audio-only calls, and when various stakeholders engaged in massive outreach to patients and in efforts to improve digital literacy.[52] In a public letter, the National Association of Insurance Commissioners expressed that the delivery of telehealth services must be complemented by the above steps to avoid preventing health inequities.[53]

In essence, simply offering telehealth coverage is not enough. **Health plans, providers, as well as federal, state, and local governments must invest in making telehealth accessible, particularly for underserved populations.** As a Whaley et al. study indicates, when plans invest in offering telehealth services, everyone takes advantage of them, especially underserved communities. These researchers found that when adjusting for integrated health plan enrollment, differences in telehealth utilization that take into account race and ethnicity, income, and language diminished.[54] They added that the most important factor in telehealth utilization was health plan enrollment, and in particular, whether it was an

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[50] *See* Christopher M. Whaley et al., *The Health Plan Environment in California Contributed to Differential Use of Telehealth During The COVID-19 Pandemic,* 41 HEALTH AFF. 12 (2022). *See also* Jasmine De Silva et al., *Startup innovation for underserved groups: 2021 digital health consumer adoption insights* (May 16, 2022), https://rockhealth.com/insights/startup-innovation-for-underserved-groups-2021-digital-health-consumer-adoption-insights/?utm_source=newsletter&utm_medium=email&utm_campaign=pro_deals_healthtech_subs&stream=top (proving that Medicaid recipients are utilizing telehealth at similar rates than the actual average and that LGTBQIA+ individuals are using telehealth at even higher rates).

[51] *See* Sanuja Bose et al., *Medicare Beneficiaries in Disadvantaged Neighborhoods Increased Telemedicine Use During The COVID-19 Pandemic*, 41 HEALTH AFF. 5 (May 2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01706.

[52] Research has shown that telephone and audio-visual interventions can provide an effective mode of treatment for a wide range of behavioral health conditions, including more severe conditions and SUD. Providers have highlighted that audio-only services can be an effective method of providing services, especially for engaging contemplative or pre-contemplative individuals in care (e.g., those who are skeptical about or question the benefit of counseling). *See Innovations in Telehealth in Mental Health and Substance Use During Covid-19*, *supra* note 40.

[53] Whaley et al., *supra* note 50.

[54] *Id.*

integrated versus a nonintegrated health plan.[55] A health plan that clinically and financially integrates providers and payers, the report concluded, had higher and more equitable use of telehealth during the COVID-19 pandemic.[56]

Utilization of Telehealth in the Context of Mental Health and Substance Use Disorders

Telehealth has been particularly effective in increasing access to mental health and SUD services during the COVID-19 pandemic and advocates have pushed for permanent adoption of many of these telehealth-related policies. Evidence shows that of all health benefits, behavioral health services have the highest uptake of the telehealth modality among consumers.[57] We believe HHS should require plans to adopt standards for telehealth specific to behavioral health. These standards should enable plans to offer all behavioral health services via telehealth and should emphasize the need to offer telehealth services at the same rates as in-person services.

We believe that telehealth holds significant promise in terms of expanding access to MH/SUD benefits in the context of QHPs. Telehealth is a growing, effective way to provide MH/SUD care when patients and providers are in different physical locations. Virtual access to MH/SUD services continues to fill a great need and improve access to care for individuals without transportation, individuals in communities where there are no local treatment options for specialized care, individuals residing in areas with inclement weather, and for individuals with co-occurring conditions that make it feasible to participate in treatment from home whereas their condition would normally result in a no-show appointment. For mental health conditions that need specialty care such as eating disorders, studies show in-person versus virtual therapy in outpatient eating disorder treatment find short-term clinical outcomes (i.e., eating symptoms, levels of weight gain (as applicable), and patient satisfaction with services) were comparable. In some populations, like children and adolescents, it may also create a better experience than traditional therapy sessions. Additionally, telehealth can increase access to culturally competent and clinically specific clinicians for underserved individuals.

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[55] *Id.*
[56] *Id.*
[57] Justin Lo et al., Kaiser Fam. Found., *Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic* (March 15, 2022), https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/.

It is important to note that telehealth is a platform for service delivery, not a discrete benefit. Plans should maintain a hybrid model in which all methods of service delivery, including in-person and telehealth, should be covered allowing consumers to elect how to receive services, in consultation with their provider. HHS should also ensure that any standards related to coverage for telehealth conform to other proposed regulatory standards, such as those proposed by SAMHSA on Medications for the Treatment of Opioid Use Disorders, 42 C.F.R. Part 8, including initiation of buprenorphine treatment by audio-visual and audio-only telehealth and methadone treatment by audio/visual telehealth.

- *What other strategies have plans implemented to broaden access to telehealth services?*

Health plans should reimburse providers for offering services through all telehealth technologies and modalities: synchronous/live video-conferencing, audio-only, asynchronous or store and forward, e-consults, and remote patient monitoring.[58] They should allow patients—in consultation with their providers—to choose what method they would like to use for a telehealth visit.[59] Furthermore, plans should reimburse all types of providers—whether they are physicians, nurses, pharmacists, or others—who can deliver telehealth services while meeting their professions' standards of care.

As broadband has yet to achieve universal reach and digital awareness slowly increases, payers must reimburse telephone and audio-only interventions. Research shows that audio-only services can become effective modes of treatment for a large number of services, including behavioral health.[60] In addition and as indicated above, providers have expressed that some patients prefer audio-only services or other non-video-conferencing services, especially for those who might experience shame and trauma.[61] Duke University researchers found that Black Medicaid recipients as well as those who qualified for the program due to

[58] For an explanation on each telehealth modality, see Fabiola Carrión, Nat'l Health Law Prog, *Medicaid Principles on Telehealth* (May 11, 2020), https://healthlaw.org/resource/medicaid-principles-on-telehealth/.
[59] *Id*. *See also* The Child. P'ship, *Telehealth and Children of Color with Special Health Care Needs: Lessons from the Pandemic*, (Sept. 2022), https://childrenspartnership.org/wp-content/uploads/2022/09/TCP_Telehealth_Full-Brief-FINAL-9.22.22.pdf [hereinafter *Telehealth and Children of Color with Special Health Care Needs*].
[60] *See Innovations in Telehealth in Mental Health and Substance Use During Covid-19*, *supra* note 40, at 3.
[61] *Id.* at 14.

pregnancy or disability used audio-only visits more than video visits.[62] Audio-only behavioral health visits for rural and Indigenous Medicaid beneficiaries also had high rates of audio-only visits.[63]

Additionally, plans should expand coverage of telehealth services in trusted places in the community like schools and early learning centers.[64] They should be mindful of disparities, assessing for digital literacy and reimbursing community health workers (also known as promotores) who can teach and help patients navigate telehealth interventions as well as covering digital equipment and software necessary for telehealth visits.[65] Like with in-person services, services delivered through telehealth should be culturally competent and linguistically appropriate. To this end, language interpreters should also be available to individuals accessing care through telehealth.[66]

A word of caution, however. While telehealth can make it easier for people to access providers, they should not be forced to use telehealth for their care. As such, no plan policy or practice should discourage in-person visits, such as by increasing copayments for in-person visits compared with a telehealth visit. In addition, the use of telehealth should not derail network adequacy and other managed care protections. More specifically, plans should not require patients to utilize telemedicine in lieu of receiving in-person services from an in-network provider when there is not a public health emergency.

B. Changes in Medical Evidence and Scientific Advancement

Question: We seek comment on whether and to what extent the EHB need to be modified or updated to account for changes in medical evidence and scientific advancement.

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[62] *See* Clarissa Donnelly-DeRoven, *Has telehealth democratized care? It's complicated*, NC Health News (July 19, 2022), https://www.northcarolinahealthnews.org/2022/07/19/has-telehealth-democratized-care-its-complicated/.
[63] *Id.*
[64] *See Telehealth and Children of Color with Special Health Care Needs*, *supra* note 59.
[65] *See id.* (explaining that community health workers can become digital navigators, helping patients have access to and can use information technologies, including affordable Internet, Internet-enabled devices, technical skills and application support).
[66] *See* Carrión, *supra* note 58.

- *What changes in medical evidence and scientific advancement have occurred since 2014 that are not reflected in the current EHB-benchmark plans? Are there benefits widely covered as EHB that are not supported by current medical evidence?*

HHS must take into account changes in medical evidence and scientific advancement when updating the EHBs. The United States' maternal mortality rate has worsened during the last three decades with considerable racial disparities.[67] New interventions are needed to address the maternal mortality rate. Updating the maternal health category of EHBs is a crucial step to improving maternal health and reducing the high rates of maternal mortality in the U.S. We urge HHS to take bold action for parents and children.

Maternity care should be consistent with the joint Guidelines for Perinatal Care from the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) (hereinafter "Joint Guidelines").[68] This includes full-spectrum doula care, midwife services, and maternal oral health services.

Doulas are non-clinical, typically perinatal health workers who provide advocacy, health education, emotional and physical support, and individualized care during the prenatal period, labor and delivery, and postpartum period.[69] Full-spectrum doula care includes care during other end of pregnancy situations like abortion, miscarriage, and stillbirth.[70] The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal

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[67] CDC, Pregnancy Mortality Surveillance System, https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm (last visited Jan. 31, 2023). *See also* CDC, Working Together to Reduce Black Maternal Mortality (Apr 6, 2022), https://www.cdc.gov/healthequity/features/maternal-mortality/index.html; CDC, Racial/Ethnic Disparities in Pregnancy-Related Deaths – United States, 2007–2016 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w#T1_down.

[68] Am. College of Ob. & Gyn. & Am. Academy of Ped., *Guidelines for Perinatal Care - Eighth Edition* (Sept. 2017), https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.

[69] Amy Chen & Alexis Robles-Fradet, Nat'l Health Law Prog., *Building a Successful Program for Medi-Cal Coverage for Doula Care: Findings from a Survey of Doulas in California* 7–8 (May 21, 2020), https://healthlaw.org/resource/doulareport/.

[70] *Id.* at 40.

Medicine note that the continuous presence of a doula during pregnancy is one of the most effective tools to improve labor and delivery outcomes.[71]

Doula care is well supported by extensive and reliable research. Pregnant people supported by doulas during labor and delivery are less likely to require a cesarean section or use pain medication.[72] With doula care, a pregnant person is more likely to give birth spontaneously, have a shorter labor, and report increased feelings of satisfaction with the birth experience.[73] Community-based doula care can be especially helpful for Black, Indigenous, and other people of color, as well as low-income and other underserved communities. Community-based doulas provide culturally congruent care and ensure that those with the greatest risks during pregnancy have the added support.[74] In the postpartum period, doulas are able to provide support with the transition from pregnancy to parenthood, lactation support, and emotional support.[75]

Doulas provide much needed advocacy to pregnant people. One national survey found that one in six women* reported mistreatment during childbirth, including being shouted at or scolded by a health care provider, being ignored, and having their requests for help refused.[76] Rates of mistreatment for BIPOC women were consistently higher even when comparing interactions between race and other maternal characteristics like socioeconomic status.[77]

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[71] *See* Am. College of Ob. & Gyn. & Soc'y for Maternal-Fetal Med., *ACOG/SMFM Consensus, Safe Prevention of the Primary Cesarean Delivery* (March 2014), https://www.ajog.org/article/S0002-9378(14)00055-6/fulltext.
[72] *See* Asteir Bey et al., *Advancing Birth Justice: Community-Based Doula Models as a Standard of Care for Ending Racial Disparities* (March 25, 2019), https://everymothercounts.org/wp-content/uploads/2019/03/Advancing-Birth-Justice-CBD-Models-as-Std-of-Care-3-25-19.pdf.
[73] Meghan A. Bohren et al., *Continuous Support for Women During Childbirth*, COCHRANE DATABASE SYST. REV 7(7), CD003766 (July 6, 2017), https://pubmed.ncbi.nlm.nih.gov/28681500/. Kenneth J. Gruber, Susan H. Cupito, & Christina F. Dobson, *Impact of Doulas on Healthy Birth Outcomes*, 22 J. PERINAT EDUC. 49 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3647727/. Nan Strauss, Katie Giessler, & Elan McAllister, *How Doula Care Can Advance the Goals of the Affordable Care Act: A Snapshot From New York City*, 24 J. PERINAT. EDUC. 8 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4720857/.
[74] Chen & Robles-Fradet, *supra* note 69.
[75] *Id.* at 5.
[76] Saraswathi Vedam et al., *The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States*, 16 REPROD. HEALTH 77 (2019), https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2.
[77] *Id.*

Doulas are uniquely positioned to provide advocacy to the pregnant person and help mitigate the harmful effects of institutional bias in medical settings.

At a minimum, three prenatal and three postpartum doula visits should be covered in addition to separately covering labor and delivery or other end of pregnancy instances. This coverage must be inclusive of the wide variety of doula training models, traditions, and practices, including those by community-based doula groups and BIPOC doula trainers.

Research also demonstrates that access to midwifery care, home births, and birthing at birth centers results in positive outcomes.[78] Exposure to COVID-19 has increased the interest in home births.[79] Pregnant people are selecting prenatal care and support away from the hospital and clinic settings that may increase their exposure to COVID-19. This should be supported by requiring plans to cover every type of qualified midwife, including certified nurse midwives and certified professional midwives. Both midwives and doulas should not be subjected to physician supervision.

Maternal oral health should be included in the maternal care benefit to be consistent with the Joint Guidelines. The Joint Guidelines lists dental care as an area of concern and notes the common oral health concerns during pregnancy. In fact, pregnancy itself increases the risks for oral health concerns.[80] Oral health conditions can be harmful to the health of the pregnant person and the future health of their child.

Pregnancy impacts oral health in several ways. The American Dental Association (ADA) notes that cavities may increase due to the changes in diet and increased acidity and erosion from increased vomiting during pregnancy.[81] According to the CDC, approximately 60 to 70 percent of pregnant women have gingivitis, an early form of periodontal disease that can be worsened

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[78] *See* Laurie Zephyrin et al., The Commonwealth Fund, *Community-Based Models to Improve Maternal Health Outcomes and Promote Health Equity* (March 4, 2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/mar/community-models-improve-maternal-outcomes-equity.

[79] *See, e.g.*, Rachel Scheier, *Black Women Turn to Midwives to Avoid COVID and 'Feel Cared For'*, California HealthLine (Sept. 16, 2020), https://californiahealthline.org/news/black-women-turn-to-midwives-to-avoid-covid-and-feel-cared-for/.

[80] Zeynep Yenen & Tijen Ataçağ, *Oral Care in Pregnancy*, 20 J. TURK. GER. GYNECOL. ASS'N 264 (Dec. 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6883753/.

[81] Am. Dental Ass'n, Pregnancy, https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/pregnancy (last visited Jan. 31, 2023).

due to changing hormones during pregnancy.[82] ACOG estimates that approximately forty percent of pregnant women have some form of periodontal disease.[83]

Research also shows that a pregnant person's oral health may have longer term effects on their child. Children of birthing parents who have higher levels of untreated cavities are more likely to have more cavities than those whose mothers had no untreated cavities. Further, increased levels of cariogenic bacteria in mothers can lead to increased cavities in their infants.[84] This relationship has also been observed in tooth loss. The children of mothers with higher levels of tooth loss were more likely to have more cavities compared to children whose mothers had no or moderate tooth loss.[85] 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.[86] Thus a parent's oral health care is a strong predictor of a child's oral health.[87]

Despite the safety of preventive, diagnostic, and restorative dental treatment throughout pregnancies, pregnant people are less likely to receive dental care.[88] Approximately forty-six percent of pregnant women in the U.S. report having dental cleaning during their pregnancy and this number varies depending on socioeconomic factors. Pregnant women without dental insurance are twice as likely to skip routine preventive dental care as those who have dental insurance.[89] Further, thirty-six percent of pregnant women report that it has been more than a

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[82] CDC, Pregnancy and Oral Health, https://www.cdc.gov/oralhealth/publications/features/pregnancy-and-oral-health.html (last visited Jan. 31, 2023).
[83] Am. College of Ob. & Gyn., *supra* note 71.
[84] J. Shahangian, Brushing for Two How Your Oral Health Effects Baby, https://www.healthychildren.org/English/ages-stages/prenatal/Pages/Brushing-for-Two-How-Your-Oral-Health-Effects-Baby.aspx (last visited Jan. 31, 2023).
[85] CDC, *supra* note 82.
[86] Jana Olak et al., *The Influence of Mothers' Orral Health Behavior and Perception Thereof on the Dental Health of their Children*, 9 EPMA J. 187–193 (June 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5972135/.
[87] Stefano Corbella et al., *Adverse Pregnancy Outcomes and Periodontitis: A Systematic Review and Meta-Analysis Exploring Potential Association*, 47 QUINTESSENCE INT. 193 (2016); Ben-Juan Wei et al., *Periodontal Disease and Risk of Preeclampsia: a meta-analysis of observational studies*, 8 PLOS ONE e70901 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3741358/.
[88] Am. Dental Ass'n, *supra* note 81. Cigna, *2015 Survey: Healthy Smiles for Mom and Baby - Insights Into Expecting Mothers' Oral Health Habits* (Oct. 2015), https://www.cigna.com/assets/docs/newsroom/cigna-study-healthy-smiles-for-mom-and-baby-2015.pdf?WT.z_nav=newsroom%2Fdental-study%3BBody%3BDownload%20Executive%20Summary.
[89] Am. Dental Ass'n, *supra* note 81. Cigna, *supra* note 88.

year since their routine dental visit, and twenty-eight percent note that they have not received routine dental care in at least two years. 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.[90] 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.[91] Similarly, other studies show that, among adults who had not visited the dentist within the past year, fifty-nine percent noted cost as the reason.[92] 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. A step to ease financial barriers is to include dental care as an EHB; even more pressing with our national crisis of maternal health is to include dental care as the maternal health benefit.

- *Are there other barriers to incorporating changes in medical evidence and scientific advancement into the EHB? How can the EHB better track with changes in medical evidence and scientific advancement? What steps should be taken to address EHB that are not supported by current medical evidence? How might the EHB adapt to more quickly address pressing public health issues such as public health emergencies (e.g., overdose epidemic) and maternal mortality rates (particularly among underserved populations)?*

We believe the best way to account for changes in medical evidence and scientific advancement in EHB coverage is for HHS to fulfill its duty to periodically review and update EHB. To our knowledge, HHS has not conducted such a review and submitted a report to Congress to date and this delay has led to widening gaps in access to certain services. **Rather than wait for occasional reviews, HHS should establish a standard framework for reviewing and updating EHBs. This is not only a statutory requirement, but also a fundamental policy requirement. The process for review of the EHB must be**

[90] Am. Dental Ass'n, *supra* note 81. Cigna, *supra* note 88.
[91] Am. Dental Ass'n, Oral Health and Well-Being in the United States, https://www.ada.org/resources/research/health-policy-institute/coverage-access-outcomes/oral-health-and-well-being (last visited Jan. 31, 2023).
[92] 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. 12, 2176–2182 (2016), https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0800.

transparent, with mechanisms in place to allow for regular and meaningful public review and comment.

The EHB review and updating process should be consumer-focused and data-driven to identify and address EHB coverage gaps and close health disparities.[93] This approach implements the ACA and the Biden-Harris Administration's commitment to "protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American," and "advance equity for all, including people of color and others who have been historically underserved."[94]

Identifying Barriers and Gaps in Access to Care

HHS should regularly review benefits packages to ensure that certain populations or specific diseases or conditions are not adversely affected by the services or level of coverage offered and that covered benefits reflect the standard of care and current clinical approaches. We recommend a standard review process that takes place, at a minimum, every other year.

The process for review of the EHB packages must be transparent, with mechanisms in place to allow for regular and meaningful public review and comment. HHS should establish ongoing mechanisms available to track access to health services and potential obstacles in accessing services due to coverage limitations or cost. EHB data collection should include:

1. Periodic review, analysis, and comparison of state base benchmark plans in EHB benefit categories;[95]

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[93] We note that the Institute of Medicine, in a 2011 report, discusses possible features of an EHB review process. While many of the report's assumptions and priorities are outdated, some IOM recommendations remain relevant and are reflected herein. *See* Inst. of Med., *Essential Health Benefits: Balancing Coverage and Costs* (2011), https://nap.nationalacademies.org/read/13234/chapter/1#xxii.

[94] Exec. Order No.14,009, Strengthening Medicaid and the Affordable Care Act, 86 Fed. Reg. 7793-7795 (Feb. 2, 2021), https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02252.pdf. Exec. Order No. 13,985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 Fed. Reg. 7009-7013 (Jan. 25, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf.

[95] *See, e.g.*, Charley E. Wilson, Phillip M. Singer, & Kyle L. Grazier, *Double-edged Sword of Federalism: Variation in Essential Health Benefits for Mental Health and Substance Use Disorder Coverage in States*, 16 HEALTH ECON., POL'Y & L. 170 (2021), https://pubmed.ncbi.nlm.nih.gov/31902388/.

2. Review issuer claim denials, utilization management, and consumer complaints; HHS should have a system in place for monitoring these reports as well as the outcomes (appeals/overrides) to provide early warnings of what types of problems consumers are encountering;[96]
3. Population-based health data tracking health trends, outcomes, and unmet health needs.[97]

The HHS EHB review can rely, in part, on existing data sources and analyses. In addition, agencies within HHS can coordinate their efforts to review and update EHB.[98]

Meaningful Stakeholder Engagement

HHS should create an advisory council to assist in reviewing and updating EHBs. Patient and consumer representatives should be adequately represented on this council and properly compensated for time spent in council-related activities. There should be flexibility available to

[96] A recent study of ACA Marketplace plans by the Kaiser Family Foundation found that issuers denied 1 in 5 claims. Some plans denied up to eighty percent of claims. Yet only .1% of denials are ever appealed to the first level; and only 2,100 of denied claims were appealed to external review. *See* Karen Pollitz, Matthew Rae, & Salem Mengistu, Kaiser Fam. Found., *Claims Denials and Appeals in ACA Marketplace Plans in 2020* (July 5, 2022), https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/?utm_campaign=KFF-2022-Private-Insurance&utm_medium=email&_hsmi=218624983&_hsenc=p2ANqtz-8uT0YrfvPbX_L6xr90SSjNAxPwvB6_j3FaeL-PS1URqC2rmoaGizrH7kllZpQOUtzXGrgapwq6Qp0NICigJNkXdc9W5A&utm_content=218624983&utm
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[97] *See, e.g.*, CDC, Behavioral Risk Factor Surveillance System, https://www.cdc.gov/brfss/index.html (last visited Jan. 31, 2023); CDC, Youth Risk Behavior Surveillance System, https://www.cdc.gov/healthyyouth/data/yrbs/index.htm (last visited Jan. 31, 2023); CDC, National Health Interview Survey, https://www.cdc.gov/nchs/nhis/index.htm (last visited Jan. 31, 2023).

[98] For example, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) issued a report, Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces (Dec. 28, 2021), which bolstered a rulemaking from the HHS Center for Consumer Information and Insurance Oversight (CCIIO) establishing requirements for standardized plans in ACA Marketplaces. *See* ASPE, *Facilitating Consumer Choice: Standardized Plans in Health Insurance* Marketplaces (Dec. 28, 2021), https://aspe.hhs.gov/reports/standardized-plans-health-insurance-marketplaces#:~:text=Standardized%20plans%20are%20a%20policy,and%20cost%2Dsharing%20across%20plans; HHS, Dep't of Treasury, Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond, 86 Fed. Reg. 53412–53506 (Sept. 21, 2021), https://www.govinfo.gov/content/pkg/FR-2021-09-27/pdf/2021-20509.pdf.

HHS and the advisory council to make recommendations as to how benefits could be modified to address identified gaps in access. Further, the council should have the authority to monitor changes and developments in medical evidence, and recommend updates to the benefits package to reflect those changes in a timely manner. In addition, there should be a public notice and comment process to address updates and full transparency on advisory council proceedings and materials. HHS should ensure the participation of underserved and disenfranchised populations, including BIPOC, persons with disabilities, members of tribal communities, LGBTQ+ persons, and other underrepresented communities.

The EHB advisory group should follow best practices including holding public meetings, soliciting public comment, have staggered terms to ensure continuity, for-cause removal mechanisms, and rigorous disclosure and conflict of interest protocols. HHS should consider modeling the advisory group after other permanent structures like the CMS Core Set Working Group, the Advisory Committee on Minority Health, or the HRSA Advisory Committee on Training in Primary Care Medicine and Dentistry.

Advancing Health Equity

A data-driven, transparent, and participatory review process should identify unmet health needs and help prioritize what benefits and services states should add when updating their EHB benchmark plans. States should be mindful that some data resources do not provide a detailed breakdown of key factors such as race, disability, sexual orientation, gender identity, and sex characteristics. All information collected and reported should be made publicly available, with opportunities to provide comment, and no charge should be required to access this information.

A system of regular, standardized surveys should be used with both quantitative rating and qualitative experience reporting to assist in determining whether enrollees are facing difficulty in accessing coverage due to cost, unlawful practices, or other barriers.[99]

[99] For example, the Federal Employee Health Benefits program can be an instructive model in this context. This program conducts an annual survey of a random sample of plan members to assess satisfaction with plans. The indicators include: overall plan satisfaction, getting needed care, speed of getting care, provider communication, customer service, claims processing, and plan information on costs. This information is publicly available to members so they can compare results across plans (generally surveys are only available for those plans with more than 500 subscribers). *See* Office of Personnel Management, *2019 Federal Employee Benefits Survey Report* (April 2020),

Current and innovative survey and reporting methods and designs should be utilized to ensure that information received is based on sound protocols and guidelines. Surveys must be tested with a variety of audiences, including low-income, Limited English Proficient individuals, individuals with hearing or vision disabilities, and other vulnerable populations to ensure that comprehension and usability is maximized and the surveys are meaningful. All major stakeholders, including clinicians, administrators, and consumers, should have an opportunity to provide feedback via the survey.

- *How should EHB advance health equity by taking into consideration economic, social, racial, or ethnic factors relevant to health care access? How can EHB better address health conditions that disproportionately affect underserved populations?*

HHS must take a data-driven approach when reviewing and updating EHB coverage. A data-driven approach includes analysis of differences in health care access and utilization by different populations. Different groups of people have different health needs; for example, a Transgender woman may have different reproductive or sexual health needs than a cisgender woman. Different groups of people may also experience disparities based on access to care and other non-medical or structural factors. Asthma, which requires specialized treatment, disproportionately affects Black, Indigenous, and other People of Color (BIPOC). HHS can ensure types of care relied on by specific populations remain available by including this care in EHB coverage. In this way, HHS can develop a process of using regular EHB review to advance health equity and to be inclusive of the health needs of underserved populations.

However, HHS cannot effectively understand whether current and future EHB standards meet the needs of various populations without studying what those needs are. To support HHS' overall equity mission, HHS must first adopt a standardized method of collecting demographic information in its programs and activities and using that demographic information to stratify measures of health care access, quality, outcomes, utilization, and more. We recommend that HHS adopt baseline uniform standards for collecting information on individuals' race, ethnicity, written and spoken language, age, disability status, sexual orientation, gender identity, and variations in sex characteristics. Please see our detailed recommendations on demographic data collection in HHS programs in our comments on the 2022 Proposed Rule on

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https://www.opm.gov/policy-data-oversight/data-analysis-documentation/employee-surveys/2019-federal-employee-benefits-survey-report.pdf.

Nondiscrimination in Health Programs and Activities.[100] Where states carry out programs on behalf of HHS, such as an ACA Marketplace or Medicaid program, HHS must require states to collect the same uniform demographic information on program participants.

HHS must incorporate demographic data analysis in its regular EHB review to ensure that health care services utilized by a range of demographic groups are represented in the EHB coverage. HHS must also make clear that states that set benchmark plans must consider utilization of health care services and health needs of different demographic groups when selecting EHBs and benchmark plans. In many cases, states can review demographic data available from large health surveys such as the Behavioral Risk Factor Surveillance System (BRFSS) and the Youth Risk Behavior Surveillance System (YRBSS) to understand health needs of various demographic groups. However, not all states collect information about sexual orientation, gender identity, or disabilities on these health surveys, and so demographic information is not uniformly available. Thus, HHS needs to set a standard of uniform demographic data collection in its programs to generate a source of ongoing real time information about the health needs of various populations. For example, by requiring a standard set of demographic information to be collected on the single, streamlined application, and using that information to stratify health needs by demographics, HHS can use that data analysis to inform EHB coverage in its regular EHB review.

We also note that HHS has extensive authority to address language access barriers among QHPs by ensuring adequate language services for persons with limited English proficiency (LEP). According to the most recent data, sixty-three percent of LEP individuals are Latinx and twenty-one percent are Asian/Pacific Islander.[101] Moreover, according to one study, a "substantial number of Asian Americans reported encountering racial discrimination and possessing limited English proficiency."[102] Another study revealed that "more than half (sixty-

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[100] HHS, CMS, Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824–47920 (Sept. 21, 2021), https://www.govinfo.gov/content/pkg/FR-2022-08-04/pdf/2022-16217.pdf. Nat'l Health Law Prog., *Comments on Section 1557 Proposed Rule* (Oct. 3, 2022), https://healthlaw.org/resource/nhelp-comments-on-section-1557-proposed-rule/. We request that HHS also consider our asks on demographic data collection from our prior comments on the Proposed Rule on Nondiscrimination in Health Programs and Activities as incorporated into this RFI.

[101] Migration Pol'y Inst., *The Limited English Proficient Population in the United States in 2013* (July 8, 2015), https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013.

[102] Gilbert C. Gee & Ninez Ponce, *Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California*, 100 AM. J. PUB. HEALTH 888 (May 2010), https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2009.178012.

five percent) of [patients in the study] indicated that they have felt discriminated against by [health care] staff because of their Hispanic ethnicity or LEP."[103] Improving language access services is therefore a critical tool to addressing discrimination against people of color through limited language access services.

Improving health care access for people living with disabilities is critical to reducing racial health disparities. Black people are more likely to have a disability relative to White people in every age group, and according to the National Disability Institute, fourteen percent of Black people live with disabilities compared to eleven percent of Non-Hispanic Whites and eight percent of Latinos.[104] Accordingly, we support HHS moving to incorporate consideration for LEP in any future EHB review and update process. HHS should analyze the existence, or lack thereof, of QHP policies to address LEP and should adopt policies, at the federal level, to ensure that plans are complying with nondiscrimination requirements related to LEP.[105]

C. Addressing Gaps in Coverage

Question: We seek comments on how the EHB could be modified to address any gaps in coverage or scope of benefits

- Are there examples of benefits that are essential to maintaining health, including behavioral health, that are insufficiently covered as EHB but that are routinely covered by other specific health plans or programs, such as employer-sponsored plans, Medicare, and Medicaid? To what extent does the EHB cover screening, consultative, and treatment modalities that supports the integration of both mental health and substance use disorder services into primary care?

In the past, NHeLP has submitted letters to CCIIO advocating for a federal definition or standard for some of the ten listed EHB categories, that would establish minimum

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[103] William A. Calo et al., *Experiences of Latinos with Limited English Proficiency with Patient Registration Systems and their Interactions with Clinic Front Office Staff: an exploratory study to inform community-based translational research in North Carolina*, 15 BMC HEALTH SERVS. RSCH. 570 (2015), https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1235-z.
[104] Nanette Goodman, et al., Nat'l Disability Inst., *Financial Inequality: Disability, Race and Poverty in America*, https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf.
[105] Nat'l Health Law Prog., *supra* note 100.

requirements for services for which coverage is currently lacking.[106] Below, we reemphasize many of these recommendations and provide further detail to answer HHS' specific questions.

Rehabilitative and Habilitative Services and Devices

Many people with disabilities and chronic conditions still struggle to access the rehabilitative and habilitative services and devices ("RHSD") that they need to maintain their health and functioning, pursue education and employment, and participate in their communities.[107] Critical health care items like Durable Medical Equipment and medical foods, which are routinely covered by Medicare, Medicaid programs, and most plans offered in large group markets, are often overlooked or purposefully excluded by individual and small group plans.

HHS helped address gaps in coverage in the RHSD EHB category by adopting a federal minimum definition for habilitative services and devices, and requiring plans to cover habilitative services on par with rehabilitative services.[108] However, plans are still regularly excluding essential services and devices, like wheelchairs, breathing aides, and glucose monitors, that constitute the standard of care for people with certain conditions. As detailed below, **we recommend that HHS further clarify the scope of covered benefits in the RHSD category to ensure that the basic needs of health care consumers are met.**

Durable Medical Equipment (DME)

In many states, people with disabilities or chronic conditions cannot access needed DME, such as wheelchairs, ventilators, hearing aids, and infusion pumps.[109] Advocates and consumers

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[106] *NHeLP Letter Re: Advancing Health Equity Trough EHB*, *supra* note 1.
[107] Rehabilitative and habilitative services and devices are health care services and devices that help a person "attain…regain, maintain, or prevent deterioration of a skill or function" that was either "never learned or acquired due to a disabling condition" or "lost or impaired due to illness, injury, or disabling condition." HHS, Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,750, 10,811 (Feb. 17, 2015), https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.
[108] 45 C.F.R. § 156.115(a)(5).
[109] Durable medical equipment are rehabilitation and habilitation devices that are designed for repeated use, intended to treat a medical condition or injury, and used to improve or maintain an individual's functioning and ability to perform activities of daily living, such as breathing, mobility, using the restroom, and monitoring one's health. Additional examples of DME include ambulation devices, such as walkers, canes, and gait trainers; bathroom equipment; blood glucose monitors; blood pressure equipment; hospital beds; CPAP and BIPAP machines; oxygen supplies; patient lifts and standing

have reported that health plans subject to the EHB requirements often exclude or severely limit coverage of DME, causing adults and children to go without medically necessary devices, obtain inferior ones that put their health and safety at risk, or turn to publicly-funded health care programs to fill in the gaps.

For the individuals who need it, DME is critical to maintaining or improving basic human functions, like ambulation, breathing, and receiving nutrition. For example, wheelchairs enable people with mobility disabilities to become mobile, remain healthy, and participate fully in community life. An appropriate wheelchair can increase an individual's physical function, level of activity, and control over their own bodies and movements. With proper fitting and customization, it can improve respiration and digestion, prevent life-threatening pressure sores, minimize joint sprain and pain, and reduce the progression of an individual's impairment or secondary conditions. It also increases access to health care by facilitating travel to the doctor's office, physical and occupational therapy, mental health providers, and the pharmacy. Maintenance of health, in turn, improves quality of life and decreases future health care expenses.[110]

Despite the importance of DME, health plans continue to exclude coverage of DME or place annual dollar limitations, high cost-sharing, and/or "home use" rules on their coverage. As an example, consider the coverage (or lack thereof) of DME in California's EHB benchmark plan. While the California benchmark includes some low-cost DME items, such as canes, crutches, and IV poles, it excludes other highly critical DME items, such as wheelchairs, CPAP machines, and hospital beds.[111] Additionally, of the short list of low-cost DME items that the

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systems; pneumatic compressors; and wound therapy devices. Medical professionals determine what type of DME is medically necessary and appropriate for the user.

[110] *See, e.g.*, World Health Org., *Guidelines on the Provision of Manual Wheelchairs in Less Resourced Settings* 23 (2008), https://www.who.int/publications/i/item/9789241547482; Alicia M. Koontz, et al., *Wheeled Mobility*, 2015 BIOMED. RESEARCH INT'L (April 1, 2015) (Editorial) (introducing Special Issue focused on wheelchairs), https://www.hindawi.com/journals/bmri/si/701370/; Silvia Yee et al., Disability Rts. Educ. and Def. Fund et al., *Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity* (2017), https://dredf.org/wp-content/uploads/2018/01/Compounded-Disparities-Intersection-of-Disabilities-Race-and-Ethnicity.pdf.

[111] The State of California selected the Kaiser Small Group HMO 30 plan, as offered in the first quarter of 2014 and as supplemented by additional State requirements, as its EHB benchmark plan. *See* CAL. HEALTH & SAFETY CODE § 1367.005(a)(2)(A); CAL. INS. CODE § 10112.27(a)(2)(A). Implementing regulations codify the benefits included within this plan, and define the RHSD category to only include a list of nine DME items: canes, crutches, dry pressure pads, IV poles, enteral pumps, bone stimulators, cervical traction, phototherapy blankets, and some dialysis equipment. *See* CAL. CODE REGS. tit. 28,

California benchmark does cover, they are only covered to the extent they are "intended for use in the home."[112] This means, for example, that if an individual can move around their home with a walker or by crawling, but they need a wheelchair to travel even 10 feet outside their home, then only the walker would be covered.

California's EHB benchmark plan has caused most health plans offered in the State's individual and small group markets to exclude critical DME items. Even when plans do offer more comprehensive DME coverage, many still impose $2,000 annual dollar limitations, 100 percent co-insurance rates, and home use rules.[113] Without adequate insurance coverage, these devices are cost prohibitive for most individuals and families. We have received reports of people resorting to hardware store fixes to keep their 15-year-old wheelchairs moving; children using devices they have outgrown and developing pressure sores because of it; and adults quitting their jobs or taking lower salaries in order to qualify for Medicaid, which offers better DME coverage.

When Congress enacted the ACA and decided to include "rehabilitative and habilitative services and devices" as an EHB category, this was not the result it intended. To the contrary, legislative history supports explicit inclusion of DME as an EHB and *without* any home use limitations.[114]

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§ 1300.67.005(d)(5)(C); CAL. CODE REGS. tit. 10, § 2594.3(a)(4). Notably absent from this list is a number of quintessential DME items that happen to be more expensive, such as wheelchairs, ventilators, and hearing aids are not included on this list. *See* CAL. CODE REGS. tit. 28, § 1300.67.005(d)(5); CAL. CODE REGS. tit. 10, § 2594.3(a)(4).

[112] *See* CAL. CODE REGS. tit. 28, § 1300.67.005(d)(5); CAL. CODE REGS. tit. 10, § 2594.3(a)(4).

[113] For context, DME items can cost anywhere from $400 to $50,000. For example, a typical manual wheelchair costs $4,000; a typical power wheelchair costs $15,000. With a $2,000 annual dollar limitation, the plan would only cover a small fraction of the cost of the medically necessary device. 100 percent coinsurance rates means that the beneficiary would pay 100 percent of the cost of the DME item, up to the out-of-pocket maximum.

[114] Upon passage of the ACA, Representative George Miller (Chair of the House Energy and Commerce Committee and co-author of the bill) expressed his understanding that "[t]he term 'rehabilitative and habilitative devices' includes durable medical equipment" and "will not be limited to 'in-home' use only." 111 Cong. Rec. 1882 (March 21, 2010). *See also* Statement of Rep. William Pascrell, 111 Cong. Rec. 463 (March 23, 2010) ("The term 'rehabilitative and habilitative devices' includes durable medical equipment, prosthetics, orthotics, and related supplies. It is my understanding that the [ACA] requires the Secretary of HHS to develop, through regulation, standard definitions of many terms, including durable medical equipment, for purposes of comparing benefit categories from one private health plan to another.").

We strongly urge HHS to align with congressional intent and further define the scope of covered EHB benefits to include a minimum level of DME coverage. All plans subject to EHB should provide coverage of DME items, including manual and power wheelchairs, CPAP and BIPAP machines, ventilators, hearing aids, and hospital beds, when a health professional determines that those devices are medically necessary and appropriate. Additionally, coverage of DME should not be subject to annual dollar limitations, exorbitant cost sharing, or home use limits.

Medical Foods

In addition to DME, **we urge HHS to amend the definition of RHSD to expressly include medical foods; and require EHB plans to cover this essential component of medical treatment for many individuals with inborn errors of metabolism ("IEMs"), gastrointestinal disorders, and other conditions.**[115] Despite their essential nature, medical foods remain largely inaccessible due to their high cost. For example, medical foods and formula used to treat phenylketonuria ("PKU:), a type of IEM, cost $9,000 per year for adults. Elemental formulas, which are typically needed for people with severe digestive disorders or allergies, can cost about $50 per day.

While many health insurance plans cover medical foods, coverage is not yet uniform throughout the country and harmful limitations remain. EHB benchmark plans vary widely in their coverage of medical foods. For example:

- California: Covers "amino acid-modified products" used to treat a subset of IEMs and oral elemental formula for one GI disorder, under the pharmacy benefit. Also covers feeding tube formula for those who qualify under Medicare guidelines, billed under prosthetic and orthotic devices. Excludes all other medical foods.
- District of Columbia: Covers all medical foods for IEMs. Also covers all enteral and elemental nutrition for other conditions that CareFirst determines is medically necessary. All are billed under medical devices and supplies.
- Michigan: Covers formula used by feeding tube, which is billed as DME. Excludes all other medical foods.

[115] Medical foods are defined as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. § 360ee(b)(3).

- Mississippi: Makes no mention of any coverage of medical foods.
- North Carolina: Explicitly excludes all "formulas or special foods of any kind."[116]

While medical foods may be covered under rehabilitative or habilitative service in most instances, coverage of these services should be broadened to include all necessary services, including those that may fall outside of the RHSD category. HHS should also establish a minimum coverage standard for medical foods that requires states to ensure coverage of services to treat a variety of gastrointestinal disorders and allergies to food proteins. Moreover, for all covered conditions, states should ensure that plans cover all medically necessary foods, the medical equipment and supplies necessary to administer the food, medically necessary vitamins, and individual amino acids.

Improving rehabilitative and habilitative services can help eliminate the disparities that remain in our health care system among individuals with disabilities and older individuals. Addressing gaps in the RHSD category will also have a positive impact on people of color with disabilities. Evidence indicates that disability prevalence is highest among Black Americans, and both Blacks and Latinos are more likely to experience mobility disabilities than white individuals.[117] Expanding the rehabilitative and habilitative services that EHB plans are required to cover would go a long way in closing gaps in coverage for people with disabilities, particularly those in non-dominant racial and ethnic communities.

We urge HHS to work with consumers and other stakeholders to develop a more comprehensive national coverage standard for rehabilitative and habilitative services and devices.

Oral Health Services for All Adults

In addition to oral health services for pregnant people as part of the maternity care benefit (discussed above), we strongly urge HHS to reconsider its regulatory exclusion of oral health

[116] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb (last visited Jan. 31, 2023).
[117] Matthew Brault, U.S. Census Bureau, *Americans with Disabilities: 2005*, *Current Population Reports* P70-117 (Dec. 2008), https://www2.census.gov/library/publications/2008/demo/p70-117.pdf; Mary Bowen & Hector González, *Racial/Ethnic Differences in the Relationship Between the Use of Health Care Services and Functional Disability: The Health and Retirement Study (1992–2004)*, 48 THE GERONTOLOGIST 659 (2008), https://pubmed.ncbi.nlm.nih.gov/18981282/.

services for adults.[118] Recent research makes clear the importance of oral health care for the health and well-being of working age adults in particular. Untreated oral health conditions can increase risk for and complicate the management of other costly chronic conditions. Population-based studies have shown that periodontal disease and tooth loss are strongly associated with heart health and that good oral health can reduce the risk for cardiovascular disease[119], heart attack, atrial fibrillation, and heart failure.[120] In addition, oral health care can help identify and manage diabetes; not only are periodontal symptoms an early indicator of diabetic conditions[121], but also recent research shows that periodontal treatment can improve glycemic control and reduce hemoglobin A1C levels in diabetic patients.[122] Moreover, recent analyses of health care claims data shows that periodontal treatment has significantly reduces the cost of care for patients with type-2 diabetes and coronary artery disease.[123]

New research since the passage of the ACA also shows the importance of oral health care addressing our nation's mental health and substance use disorder (SUD) crisis. People who receive comprehensive oral health care during SUD treatment have been shown to remain in treatment longer and have improved outcomes, including employment, reduced incidence of homelessness, and abstinence from drug use.[124] It is increasingly clear that access to oral health care has a significant impact on overall health and quality of life.

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[118] *See* 45 C.F.R. § 156.115(d). Note the exclusion of "excepted" benefits from EHB is not statutory.
[119] T. Dietrich et al., *Evidence summary: the relationship between oral and cardiovascular disease*, 222 BR DENT J. 381 (March 10, 2017), https://pubmed.ncbi.nlm.nih.gov/28281612/.
[120] Yookyung Chang et al., *Improved oral hygiene care is associated with decreased risk of occurrence for atrial fibrillation and heart failure: A nationwide population-based cohort study*, 27 EUR. J. PREV. CARDIOL. 1835 (Nov. 2020), https://pubmed.ncbi.nlm.nih.gov/31786965/.
[121] Ira B. Lamster et al., *The Relationship Between Oral Health and Diabetes Mellitus*, J. AM. DENT. ASS'N (2008), https://pubmed.ncbi.nlm.nih.gov/18809650/.
[122] Phoebus N. Madianos & Panagiotis A. Koromantzos, *An update of the evidence on the potential impact of periodontal therapy on diabetes outcomes*. 139 J. CLIN. PERIODONTOL. Suppl:19S (2018), https://pubmed.ncbi.nlm.nih.gov/29277978/.
[123] Kamyar Nasseh, Marko Vujicic, Michael Glick, *The Relationship between Periodontal Interventions and Healthcare Costs and Utilization. Evidence from an Integrated Dental, Medical, and Pharmacy Commercial Claims Database*, 26 HEALTH ECON. 519 (April 2017), https://pubmed.ncbi.nlm.nih.gov/26799518/; Bijan Borah et al., *Association Between Preventive Dental Care and Healthcare Cost for Enrollees with Diabetes or Coronary Artery Disease: 5-Year Experience*, 43 COMPEND. CONTIN. EDUC. DENT. 130 (March 2022), https://pubmed.ncbi.nlm.nih.gov/35272460/.
[124] Glen R. Hanson et al., *Comprehensive oral care improves treatment outcomes in male and female patients with high-severity and chronic substance use disorders*, 150 J. AM. DENT. ASS'N 591 (July 2019), https://pubmed.ncbi.nlm.nih.gov/31122616/.

Unfortunately, lack of dental insurance and cost of care remain the primary barriers to accessing dental care, particularly for working age adults.[125] In fact, dental care presents the highest cost barriers compared to any other area of health care besides durable medical equipment.[126] Despite modest increases in access to dental insurance among adults in recent years, reported financial barriers to care have continued to increase, particularly for Black and Hispanic people.[127] Consequently, many people are forced to seek treatment for dental problems in emergency departments, resulting in high out-of-pocket costs as emergency department charges for non-traumatic dental conditions continue to climb, further exacerbating our nation's medical debt crisis.[128]

Access to oral health care is also an issue of economic justice. About one third of young adults in the U.S. and nearly 60 percent of Medicaid beneficiaries without access to dental coverage report that the appearance of their mouth and teeth affects their ability to interview for a job.[129] New research continues to add to the mounting evidence that expanding access to dental coverage wide-ranging benefits. Access to oral health coverage through recent Medicaid expansion in states like Michigan showed strengthened health and employment—including both job prospects and job performance—of low-income adults in the state.[130]

In recent years, less invasive alternatives to drilling and filling cavities have become more commonplace in dentistry. Scientific advancement and the body of evidence around the

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[125] AHRQ, *2022 National Healthcare Quality and Disparities Report* (October 2022), https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.
[126] Vujicic, Buchmueller, & Klein, *supra* note 92.
[127] Am. Dental Ass'n Health Pol'y Inst., *Cost Barriers to Dental Care Among the U.S. Population, by Race and Ethnicity* (2021), https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/hpi/hpigraphic_0421_3.pdf.
[128] CareQuest Inst. for Oral Health, *Recent Trends in Hospital Emergency Department Visits for Non-Traumatic Dental Conditions* (2022), https://www.carequest.org/system/files/CareQuest_Institute_Recent-Trends-in-Hospital-ED-Visits_6.7.22_FINAL.pdf; Lunna Lopes et al., Kaiser Fam. Found., *Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills* (June 16, 2022), https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/.
[129] Colin Reusch et al., Am. Dental Ass'n, Cmty. Catalyst, & Families USA, *Making the case for adults in all state Medicaid programs*, American Dental Association in partnership with Community Catalyst and Families USA (July 2021), https://familiesusa.org/wp-content/uploads/2021/07/HPI-CC-FUSA-WhitePaper_0721.pdf.
[130] Edith C. Kieffer et al., *Beneficiaries' perspectives on improved oral health and its mediators after Medicaid expansion in Michigan: a mixed methods study*, 82 J. PUB. HEALTH DENT. 11 (Jan. 2022), https://pubmed.ncbi.nlm.nih.gov/33754344/.

effectiveness of this “minimally-invasive care” have grown rapidly, offering options for preventive and basic restorative care that are less expensive and traumatic for patients and can reduce systems costs in the long-run.[131] Other forms of minimally-invasive care have also shown to be effective in treating disease and improving oral health, such as fluoride varnish.[132] Specified coverage of these products and procedures are in line with recent scientific advancements and hold promise for expanding accessing to critical dental care and advancing health equity. Many of them are also highlighted in the 2021 Oral Health in America report.[133]

Across HHS, there is growing recognition of emerging research linking oral health care to improved health and well-being as well as scientific advances in oral health care delivery to improve equitable access to care. CMS itself has updated its rulemaking on medically-necessary dental services in Medicare to reflect clinical evidence suggesting inextricable linkages between oral health and outcomes for other health conditions or treatments, including head and neck cancers, organ transplants, and cardiac valve replacement.[134] In reviewing and updating EHB coverage of oral health services for both children and adults, we encourage HHS to take into consideration new evidence of the essential nature of oral health care as well as emerging treatments and treatment modalities that can more effectively manage dental disease while reducing costs and improving patient experience.

Mental Health and Substance Use Disorders

Before the ACA, most health insurance plans were not required to include coverage for mental health and SUD services, despite the outstanding need for them. Regrettably, while improvements have been achieved, the benchmarking process has enabled private plans across the country to maintain significant gaps in coverage. Failure to close these gaps has exacerbated health problems associated with the opioid overdose epidemic, which continues unabated, as well as issues related to other substance use and mental health conditions. Mental health and SUD access issues are underscored by the fact that the vast majority of

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[131] Olivia Urquhart et al., *Nonrestorative Treatments for Caries: Systematic Review and Network Meta-analysis*, 98 J. DENT. RES. 14 (Oct. 2018), https://pubmed.ncbi.nlm.nih.gov/30290130/.
[132] Robert J. Weyant et al., *Topical fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review*, 144 J. AM. DENT. ASS'N 1279 (Nov. 2013), https://pubmed.ncbi.nlm.nih.gov/24177407/.
[133] HHS, NIH, Nat'l Inst. of Dental and Craniofacial Rsch., *Oral Health in America: Advances and Challenges* (2021), https://www.nidcr.nih.gov/research/oralhealthinamerica.
[134] 87 Fed. Reg. 69404.

individuals with these conditions are currently not receiving treatment.[135] According to the National Institutes for Mental Health, over half of people with a mental health condition did not receive any care in 2020.[136] Only 6.3 percent of individuals ages 12 or older who needed SUD treatment in the past year received it.[137]

In 2020, researchers published a comprehensive study of EHB benefits provided under the category for mental health and SUD services, including behavioral health treatment, after reviewing 112 EHB documents from all states from 2012 to 2017. They concluded that "[o]ur research finds notable divergence between accepted medical practice standards and the reviewed essential benefit benchmark plans standards. Coverage that does not reflect minimum standards of care threatens to harm individuals and populations and may constrain providers' ability to provide appropriate quality care."[138] Similarly, a review of the 2017 benchmark plan options (most of which are still relevant in some fashion) showed that "none of the plans provided comprehensive coverage for addiction by covering the full array of critical benefits without harmful treatment limitations," and highlighted lack of coverage for methadone maintenance therapy for opioid use disorder (OUD) as a salient concern.[139]

Given that we continue to see lack of coverage for evidence-based and effective behavioral health treatment services, we urge HHS to establish a federal minimum definition of coverage for the MH/SUD benefit category. While we believe plans should provide coverage for all services deemed medically necessary for treating any mental health or SUD condition, there are several essential services HHS should explicitly require all plans to cover for compliance with the EHB requirement to cover mental health and SUD services:

First, federal regulations should specify that EHB plans cover intensive community-based services. Provision of these services is essential to ensure access to the whole continuum of behavioral health care in the least restrictive setting appropriate for the patient's condition. When these services are not available, it leads to increased utilization of inpatient and

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[135] Nat'l Inst. of Mental Health, *Mental Health Information: Statistics*, https://www.nimh.nih.gov/health/statistics/mental-illness#part_2540 (last visited Jan. 31, 2023).
[136] *Id.*
[137] SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health* 39, 51 (2022), https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf.
[138] Wilson, Singer, & Grazier, *supra* note 95.
[139] P'ship to End Addiction, *supra* note 5.

residential settings for patients with mental health and SUD conditions, which are often ineffective and counterproductive. Lack of access to community-based services may also constitute a violation of the Supreme Court's holding in *Olmstead*.[140]

Intensive community-based services, in turn, should include access to the following services:

- Evidence-based Assertive Community Treatment (ACT), currently covered by Medicaid programs in 33 states.[141]
- Qualified community-based crisis intervention services that include, at a minimum, the core services and best practices outlined by the Substance Abuse and Mental Health Services Administration (SAMHSA), such as regional call centers and mobile crisis services.[142] Behavioral health crisis services are currently covered by Medicaid in 43 states, and since 2021 states have the option of adding mobile crisis services to their programs.[143]
- Intensive case management, which go beyond the traditional managed care case management services. Mental health and SUD intensive case management should focus on coordination of behavioral health services across the board, with non-behavioral health services, and with other supportive services that help individuals with mental health or SUD conditions in their recovery journey. Mental health case management services are currently covered by Medicaid programs in 29 states.[144]

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[140] *Olmstead v. L.C.*, 527 U.S. 581 (1999).
[141] Kaiser Fam. Found., Medicaid Behavioral Health Services: Assertive Community Treatment – 2018, https://www.kff.org/medicaid/state-indicator/medicaid-behavioral-health-services-assertive-community-treatment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Jan. 31, 2023).
[142] SAMHSA, *National Guidelines for Behavioral Health Crisis Care Best Practice Toolkit Executive Summary*, https://www.samhsa.gov/sites/default/files/national-guidelines-for-behavioral-health-crisis-services-executive-summary-02242020.pdf.
[143] Kaiser Fam. Found., Medicaid Behavioral Health Services: Crisis Services – 2018, https://www.kff.org/medicaid/state-indicator/medicaid-behavioral-health-services-crisis-services/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Jan. 31, 2023). *See also* 42 U.S.C. § 1396w-6.
[144] Kaiser Fam. Found., Medicaid Behavioral Health Services: Case Management – 2018, https://www.kff.org/medicaid/state-indicator/medicaid-behavioral-health-services-case-management/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Jan. 31, 2023).

- Peer support services, which should be provided by culturally competent individuals and/or groups. These services are covered by Medicaid programs in 32 states.[145]
- Supported employment
- Housing-related activities and services, including individual housing transition services, individual housing, and tenancy sustaining services

These services are available and typically provided under Medicaid, but are not always available in Marketplace and other private and small-group plans. We urge HHS to require all plans, in order to comply with the MH/SUD EHB requirement, to cover all these services in the most integrated manner and without limiting access to them based on disability or existence of a co-occurring SUD or history of substance use.

In addition to intensive community-based behavioral health service, we urge HHS to mandate coverage of methadone maintenance therapy under the MH/SUD category. Alongside buprenorphine, methadone is one of the most effective medications for reducing the burdens associated with OUD, and increased access to and uptake of the medication is key to addressing the ongoing opioid overdose epidemic.[146] Currently, MMT coverage under the prescription drug category standard is impaired by the fact that federal law requires provision of MMT in opioid treatment programs. As a result of this restriction, methadone is not part of the USP category of medications for OUD treatment and is often excluded from EHB plans' prescription drug coverage. A better solution would be to mandate coverage of all services that encompass MMT, including coverage for the administration of methadone at OTPs, under the MH/SUD EHB category.

Finally, we note that the responsibility to address gaps in coverage of mental health and SUD services is of heightened importance when those services are provided to children and adolescents. This population is especially vulnerable to the risks associated with mental health and substance use conditions and, as such, HHS should ensure plans are covering services specifically tailored to them. We urge HHS to standardize MH/SUD and pediatric service

[145] Kaiser Fam. Found., Medicaid Behavioral Health Services: Peer Support Services – 2018, https://www.kff.org/other/state-indicator/medicaid-behavioral-health-services-peer-support-services/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Jan. 31, 2023).
[146] NIH, How Effective are Medications to Treat Opioid Use Disorders?, https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder (last visited Jan. 31, 2023).

categories in a way that requires, at a minimum, coverage of a broad array of mental health and SUD services that are provided in community-based settings given the importance of shielding children and adolescents from the risks of institutionalization. These services should at least include Intensive Care Coordination; Crisis Services, with particular emphasis on mobile crisis services; Intensive Home-Based Services; and Therapeutic Foster Care.

As explained in more detail below, we believe HHS should in fact apply an EPSDT approach to pediatric services in the private market by requiring all plans to cover all services that are medically necessary to correct or ameliorate a condition even if the plan does not otherwise cover the service. While we support implementation of this standard for all pediatric services, however, we underscore the enormous value it would have on mental health and SUD services for children and adolescents.

- *Is there sufficient coverage as EHB of emergency behavioral health services, including mobile crisis care and stabilization services?*

A study published in 2018 showed that the vast majority of Marketplace plans (94 percent) covered mental health and substance use emergency services in 2014, up from 79 percent covering mental health emergency services and 77 percent covering SUD emergency services in 2013.[147] While more recent data is lacking, we expect this number to have continued to increase as plans fall into compliance with federal requirements. Despite these coverage gains, **HHS should urge states to update their benchmark plans to ensure proper coverage of behavioral health emergency services. In addition, covering emergency services for physical health emergencies while excluding or disparately limiting behavioral health emergency coverage constitutes a MHPAEA violation. As part of the benchmark plan parity review outlined above, HHS should monitor proper coverage of behavioral health emergency services and reject all benchmark proposals that fail to properly cover these services.**

Furthermore, **HHS should establish a standard definition of emergency services that requires all plans to cover behavioral health emergency services on equal footing as physical health emergency services. Importantly, this standard should ensure that emergency behavioral health services are effective, evidence-based, and of high quality.**

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[147] Alexander J. Cowell et al., *Behavioral Health Coverage in the Individual Market Increased After ACA Parity Requirements*, 37 HEALTH AFF. 7 (July 2018), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1517.

While most plans cover emergency services for behavioral health, most of this coverage is limited to emergency department services, which are ineffective in treating a mental health or SUD crisis.[148] Instead, HHS should emphasize the need for plans to invest in community-based emergency services that meet individuals experiencing behavioral health crises where they are.

A key component of effective emergency behavioral health care are mobile crisis services. Many plans across the country, including Medicaid programs, are beginning to include mobile crisis services in their coverage. We believe HHS should follow suit by requiring all EHB plans to cover mobile crisis services as the proper vehicle to attend to behavioral health emergencies. We also recommend that HHS implement the standards adopted by CMS for states implementing the Medicaid mobile crisis services state plan option, which include having a team of behavioral health professionals on call for behavioral health emergencies, the ability to mobilize crisis teams to any non-health facility location with few exceptions, ensuring the mobile crisis team carries essential tools to respond to an SUD crisis, such as naloxone and fentanyl testing strips, connecting individuals with follow-up behavioral health care in their communities, and limiting involvement of law enforcement in crisis response.

- *Are there differences between adult and pediatric benefits and those populations' needs such that further delineation of pediatric benefits is warranted?*

The health plans used as EHB benchmarks were developed for adults and without adequate consideration of children's health needs. A robust and comprehensive EHB is critically important for children; however, in many states the EHB benchmark approach has led to inadequate coverage of pediatric services.[149]

Concerns with the benchmarking approach are nothing new. A 2014 study found that "EHB-governed coverage, as implemented under the HHS regulations, continues to be a patchwork containing notable exclusions for children, particularly those with special needs and

[148] The Kennedy Forum, *Ensuring Coverage of Behavioral Health Emergency Services* (2022), https://www.thekennedyforum.org/app/uploads/2022/12/BH-Emergency-Servies-Brief.pdf.
[149] *See* Wakely Consulting Grp., *Comparison of Benefits and Cost Sharing in Children's Health Insurance Programs to Qualified Health Plans* (July 2014), https://www.kff.org/wp-content/uploads/sites/2/2014/07/final-chip-vs-qhp-cost-sharing-and-benefits-comparison-first-focus-july-2014-.pdf.

disabilities."[150] Researchers found specific pediatric exclusions within certain treatment categories associated with pediatric developmental and mental health conditions, including services for children with learning disabilities, speech therapy, and services for children with developmental disabilities and delays.[151]

The EHB benchmark plans do not identify separate pediatric services, therefore children receive the same coverage that adults do, with the exception of oral and vision care. A 2019 survey of EHB benchmark plans concluded that, "[b]ecause each state has its own benchmark health plan outlining the minimum scope of services to be covered, there is much variation in the pediatric services covered by states."[152]

Children are not little adults; they require services and care specifically suited to their unique developmental needs. Because of their continuous growth and development, children need timely access to a full set of pediatric and age-appropriate and family centered services. Missed screenings, diagnoses, and treatments can result in life-long health consequences that generate extensive and avoidable costs. It is critical that children's health issues are identified as early as possible, in order to avoid the development of more complex and costly issues in the future.

We underscore the importance of offering comprehensive pediatric services, including periodic health and wellness screenings, coverage of habilitative services and devices that meet children's developmental needs, and access to a full range of pediatric oral and vision services.[153]

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[150] Aimee M. Grace et al., *The ACA's pediatric essential health benefit has resulted in a state-by-state patchwork of coverage with exclusions*, 33 HEALTH AFF. 12 (Dec. 2014), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0743.
[151] *Id.*
[152] Ashley M. Kranz & Andrew W. Dick, *Changes in Pediatric Dental Coverage and Visits Following the Implementation of the Affordable Care Act*, 54 HEALTH SERV. RES. 437 (April 2019), https://pubmed.ncbi.nlm.nih.gov/30565656/.
[153] *See* Child.'s Hosp. Ass'n et al., Letter to Kevin Counihan, CCIIO, Re: Proposed 2017 Essential Health Benefits Benchmark Plans (Sept. 30, 2015).

Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is the gold standard for pediatric services.[154] We recommend that HHS establish a federal minimum definition for EHB pediatric services based on Medicaid's EPSDT benefit standard.[155]

- *To what extent could EHB better address any gaps in coverage for those with chronic and lifelong conditions?*

Congress expressly included "chronic disease management" among the ten EHB categories.[156] However, HHS has not defined "chronic disease management," which has led to a patchwork of private insurance coverage of important benefits and services that people living with chronic illness need. People with chronic illness also often struggle with high cost-sharing, with high deductibles, copays and coinsurance, and paying for services not covered by health plans.[157]

Developing a comprehensive federal coverage standard for chronic disease management is challenging, given the unique, complex, and highly individualized requirements for treating and managing a wide array of chronic conditions. Moreover, insurers often seek to discourage persons with chronic conditions from enrolling in plans. Insurance companies have used many features of health plan benefits and delivery to unlawfully deny needed coverage or discourage people with significant health needs from enrolling in their plans. These include exclusions, cost sharing, formularies and adverse medication tiering, visit limits, provider networks, prior authorization and other utilization management that are arbitrary and not clinically based or appropriate.

For example, in 2014, NHeLP and The AIDS Institute filed a HIV/AIDS discrimination complaint with the HHS Office for Civil Rights (OCR) against four Florida issuers that placed

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[154] CMS, *EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* (June 2014), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/epsdt_coverage_guide_91.pdf. *See also* Child.'s Def. Fund et al., *Defining Essential Health Benefits: What's Needed for Children?* (Dec. 2012), https://www.childrensdefense.org/wp-content/uploads/2018/08/defining-ehb.pdf.
[155] *NHeLP Letter Re: Advancing Health Equity Trough EHB*, *supra* note 1.
[156] 42 U.S.C. §1802(b)(1)(I).
[157] Nicole Topay et al., *Chronic Care Cost Cap*, The Third Way (Dec. 19, 2022), http://thirdway.imgix.net/pdfs/chronic-care-cost-cap.pdf.

all HIV medications, including generics, in the highest tier.[158] By placing even generic drugs on the top tier, patients faced high up-front costs in the form of expensive co-insurance and co-pays, as well as burdensome prior authorization requirements and quantity limits. These tactics are particularly hazardous for people living with HIV/AIDS who may have no other choice than top forego care or enroll in higher cost plans. Gaps in anti-retroviral treatment can lead to the development of drug resistance and increased rates of new HIV infections.

In a study published in the New England Journal of Medicine in January 2015, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, researchers at the Harvard School of Public Health examined forty-eight ACA health plans and found that a dozen of these plans placed medications used to treat HIV/AIDS in the highest cost-sharing tiers.[159] This practice — known as "adverse tiering" —serves to discourage people with significant health needs from enrolling in the health plan.

The Pharmaceutical Research and Manufacturers Association (PhRMA) commissioned an analysis of the formularies for 123 silver-level Marketplace plans and found similar problems regarding medications for multiple sclerosis and cancer. PhRMA concluded that there was a "lack of adequate formulary scrutiny on the part of state and federal regulators" because "[r]equiring high cost-sharing for all medicines in a class is exactly the type of practice the ACA was designed to prevent."[160]

The National Alliance on Mental Illness (NAMI) also identified adverse tiering for medications used in the treatment of mental illness in its 2015 report: *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*.[161] NAMI commissioned a study of formularies for 84 health plans to assess coverage of three classes of psychiatric medications: antipsychotics, antidepressants, and SSRIs/SNRIs used commonly to treat depression. The analysis found that many plans placed these medications on high-cost

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[158] Nat'l Health Law Prog. & The AIDS Inst., Complaint to HHS Re HIV/AIDS Discrimination by Florida (May 28, 2014), https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/.
[159] Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace*, 372 N ENGL J. MED. 399 (Jan. 29, 2015).
[160] PhRMA, *Coverage Without Access: An Analysis of Exchange Plan Benefits for Certain Medicines*.
[161] Nat'l All. on Mental Illness, *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care* 7 (April 2015), https://www.nami.org/Support-Education/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-ALongRoadAhead.

sharing tiers or with restricted access.[162] Again, individuals who need these medications often have no choice than to select costlier plans in order to access life-saving medications.

Adverse tiering can have serious consequences on chronic disease management by impeding access to potentially life-saving medications. Adverse tiering works for insurers by steering persons with significant health needs, such as HIV/AIDS, away from their plans. As a result, plans with more balanced tiering structures become more likely to enroll high-need patients. Consequently, the health plan's enrollment could become imbalanced, placing pressure on the health plan to change its coverage policies or raise premiums and/or deductibles. Yet despite statutory protections and a new regulatory framework for evaluating discriminatory benefit design, compliance and enforcement at the state and federal levels remain elusive, to the detriment of patients.[163]

With little guidance or enforcement from HHS or state regulators, it is often difficult to discern how insurers are implementing the EHB requirement to provide "chronic disease management." This has resulted in a patchwork of coverage that can be detrimental to the health of those with chronic diseases. We urge HHS to engage with patient advocates and organizations to better identify the broad range of benefits and services that define "chronic disease management." We also emphasize that any chronic disease management benefit should be comprehensive, treating the whole person and should include reproductive and sexual health. By working with stakeholders representing a diverse array of conditions and including BIPOC and others who are often underserved and under-represented, HHS should work towards a goal of establishing minimum coverage standards and ensuring that issuers meet those standards.

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[162] *Id.*

[163] *See* Carl Schmid, HIV+Hepatitis Pol'y Inst., *Discrimination in Prescription Drug Formularies*, *Presentation to the NAIC Health Innovations (B)Working Group* 19 (Dec. 13, 2022), https://content.naic.org/sites/default/files/national_meeting/schmid-formularies-fnm-2022.pdf.

Palliative and End of Life Care

Separate from "chronic disease management," people with chronic or other serious medical conditions may have unique and pressing health care needs.[164] Palliative and hospice care play crucial roles in managing the symptoms and needs of people at the end of life.

Palliative care is defined as "an interdisciplinary care delivery system designed to anticipate, prevent, and manage physical, psychological, social, and spiritual suffering to optimize quality of life for patients, their families and caregivers."[165] Palliative care is beneficial at any stage of a serious illness and can be delivered alongside curative treatment.[166] It is available in all care settings, such as in the home, outpatient care clinics, nursing homes, and hospitals.[167]

Hospice care is a type of palliative care provided to a person with a serious illness who is approaching the end of life. Hospice care "focuses on caring, not curing."[168] In addition to managing an individual's pain and symptoms, hospice assists with the emotional and spiritual aspects of dying and provides bereavement care to the family. Hospice care can be provided in the home or a facility. It can also involve respite care, which provides short-term relief for primary caregivers, allowing them crucial time to focus on other responsibilities and self-care.

Despite the importance of palliative care and hospice care to people who are seriously ill, gaps in coverage remain. State EHB-benchmark plans sometimes cover hospice care under ambulatory patient services, but the extent of coverage and scope of benefits vary widely across states. For example:

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[164] Amy S. Kelley & Evan Bollens-Lund, *Identifying the Population with Serious Illness: The "Denominator" Challenge*, 21 J. PALLIATIVE MED. S-7 (2018), https://www.liebertpub.com/doi/pdf/10.1089/jpm.2017.0548.

[165] Nat'l Consensus Project for Quality Palliative Care, *Clinical Practice Guidelines for Quality Palliative Care* (4th ed., 2018), https://www.nationalcoalitionhpc.org/wp-content/uploads/2020/07/NCHPC-NCPGuidelines_4thED_web_FINAL.pdf.

[166] *Id.*

[167] *Id.*

[168] Nat'l Hospice & Palliative Care Org., Hospice Care Overview, https://www.nhpco.org/hospice-care-overview/hospice-faqs/ (last visited Jan. 31, 2023).

- Maine: Covers hospice services up to twenty-four hours a day, provided in the home or an inpatient facility. Available to a person who has a life expectancy of twelve months or less. Services include nursing care, respite care, medical and social work services, counseling services, nutritional counseling, pain and symptom management, medical supplies and Durable Medical Equipment, occupational, physical or speech therapies, home health care services, bereavement services, and volunteer services.
- Nevada: Covers "acute care" for an individual with less than six months to live, provided in the home or an inpatient facility. Limits respite care to a maximum of five days per ninety days of home hospice care, and limits bereavement services to five group therapy sessions.
- Mississippi: Limits benefits to six "months per the lifetime" of the individual. Excludes bereavement counseling, pastoral counseling, financial or legal counseling or custodial care.[169]

In addition to this inconsistent coverage, many EHB-benchmark plan documents lack important details on the scope of coverage. For example, the Mississippi benchmark plan does not list the services that are covered under its hospice care benefit, nor what happens if an individual surpasses the six-month coverage limit.[170]

The lack of clear coverage standards for hospice care in benchmark plan documents can lead to inconsistent—and inadequate—coverage in plans subject to EHB requirements. One study analyzing managed care plans offered by companies participating in the California exchange found wide variation in hospice coverage.[171] The plans varied in the services covered, the services requiring prior approval, and length of time services are covered. Some plans did not cover certain core services—such as nurse or social worker visits—at all. Others limited coverage to just 100 days. The study also noted that some plans imposed out-of-pocket costs for hospice care through copays and high deductibles. Although visit limits and durational caps are not clinically indicated, they are common

[169] CCIIO, *supra* note 116.
[170] CCIIO, Mississippi 2017 EHB Benchmark Plan, https://www.cms.gov/cciio/resources/data-resources/ehb#Mississippi.
[171] Kyusuk Chung et al., *Assessment of Levels of Hospice Care Coverage Offered to Commercial Managed Care Plan Members in California: Implications for the California Health Insurance Exchange,* 32 Am. J. HOSPICE & PALLIATIVE MED. 440 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4160421/pdf/nihms573420.pdf.

utilization controls placed on end-of-life care. It is not clear how issuers enforce benefit limits for patients who outlive their six-month limit on hospice care.

Coverage also often fails to meet the standard of care established by the National Coalition for Hospice and Palliative Care.[172] It is also inadequate when compared to hospice coverage under Medicare and Medicaid. Both Medicare and Medicaid clearly articulate the covered services and eligibility requirements, and services are provided without any cost-sharing.[173]

A mounting body of evidence shows that palliative care and hospice care are vitally important for people who are seriously ill, their caregivers, and their family members. Numerous studies have shown that palliative care improves quality of life, symptom burden, and quality of care.[174] Family members are more likely to report excellent end-of-life care when individuals receive hospice care.[175] Hospice care also leads to decreased depression among surviving spouses.[176]

Despite these benefits, access to hospice care is unequal. Black and Latinx people are less likely to access hospice care than white people, and LGBTQ+ people face potential discrimination in end-of-life care.[177] We recommend that HHS establish federal EHB standards on end of life and hospice care, HHS can advance health equity and close a persistent gap in coverage.

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[172] Nat'l Consensus Project for Quality Palliative Care, *supra* note 165.
[173] 42 C.F.R. § 418; CMS, State Medicaid Manual § 4305.
[174] Dio Kavalieratos et al., *Association Between Palliative Care and Patient and Caregiver Outcomes: A Systematic Review and Meta-analysis*, 136 JAMA 2104 (Nov. 2016), https://jamanetwork.com/journals/jama/fullarticle/2585979; Krista L. Harrison et al., *Hospice Improves Care Quality For Older Adults With Dementia In Their Last Month Of Life*, 41 HEALTH AFFS. 821 (2022).
[175] Alexi A. Wright et al., *Family Perspectives on Aggressive Cancer Care Near the End of Life*, 315 JAMA 284 (Jan. 19, 2016), https://jamanetwork.com/journals/jama/fullarticle/2482326.
[176] Katherine A. Ornstein et al., *Association Between Hospice Use and Depressive Symptoms in Surviving Spouses*, 175 J. AM. MED. ASS'N INTERNAL MED. 1138 (July 2015), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2296014.
[177] Lisa Marsh Ryerson, *Prioritizing Health Equity in Palliative and End-of-Life Care*, GENERATIONS J. (Oct. 19, 2022), https://generations.asaging.org/health-equity-palliative-and-end-life-care.

D. Actuarial and Cost-Sharing Limitations

Question: We seek comments on the ability of plans subject to EHB requirements to conform benefit designs to these requirements.

Section 1302 of the ACA states that its review of EHBs must contain "(iv) an assessment of the potential of additional or expanded benefits to increase costs and the *interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations* described in [the TEP Provision]."[178] The ACA provides no detail on the process of actuarial certification of EHB scope at the federal level.

The Secretary has invited comments regarding how any EHB updates can still ensure that plans conform benefit design to meet actuarial certification requirements in 42 U.S.C. § 18022(b)(4)(G)(iv). At the state level a comprehensive and successful model for EHB plan design and actuarial certification has already been developed within the State EHB Benchmark Program. We encourage the Secretary to apply *this* already-developed interpretation for actuarial valuation of plans within the State EHB Benchmark Program at the federal level. This process will best allow plans subject to EHB requirements to conform benefit designs to the ACA's actuarial analysis requirements, while still ensuring health benefits are accessible in accordance with the ACA's goals.

The State EHB Benchmark Program was established by the Secretary with the express intent of complying with the TEP Provision.[179] As described above, the State EHB Benchmark Program establishes a range of benefits where the TEP is the floor, and the most generous "comparison plan" is the ceiling.[180] States have successfully conducted and submitted actuarial certifications of their EHB benchmark plans demonstrating whether the plans fall within this range.[181] The Secretary has successfully exercised statutorily-granted discretion in a

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[178] 42 U.S.C. § 18022(b)(4)(G)(iv) (emphasis added).
[179] *See* 83 Fed. Reg. 16930, 17010 ("[W]e originally established the benchmark plan policy to ensure that EHB is equal to the scope of benefits provided under a typical employer plan and in recognition that the typical employer plans differ by State.").
[180] *Id.*; *see also* 42 C.F.R. § 156.111.
[181] *See* State of South Dakota, *supra* note 17; *see also, e.g.,* State of Michigan, *Appendix B: Essential Health Benefits (EHB) – Benchmark Plan Actuarial Certification Template* (March 2, 2020), https://www.michigan.gov/-/media/Project/Websites/difs/General/Actuarial_Certificate.pdf?rev=c05130f53787479695ef17169cf769b2; State of Oregon, *Appendix B: Essential Health Benefits (EHB) – Benchmark Plan Actuarial*

reasonable way in implementing the TEP Provision. The Secretary should therefore simply apply this already-developed state process to update EHBs on a federal level.

IV. Coverage of Prescription Drugs as EHB

Question: We seek comments to confirm or further expand understanding of the risks and benefits of replacing the current USP Guidelines with a different drug classification system. Should CMS consider using an alternative prescription drug classifications standard for defining their EHB prescription drug category?

We welcome HHS' reconsideration of using the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) to establish coverage standards for EHB prescription drugs. 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. For example, the MMG fall short in covering medications essential for reproductive health, including contraception, and do not include distinct categories for FDA-approved pediatric drugs or formulations. The MMG also do not include medications covered under Medicare Part B.

United States Pharmacopeia Classification Systems

The United States Pharmacopeial Convention (USP) is a non-profit organization that sets standards for "the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide."[182] The USP's annual publication, the United States Pharmacopeia-National Formulary (USP-NF), is the official compendia, or compilation, of drugs marketed in the United States.[183]

Certification Template (April 29, 2020), https://dfr.oregon.gov/help/committees-workgroups/Documents/2019-ehb-committee/actuarial-certification-EHB.pdf.

[182] *See* United States Pharmacopeial Convention, About U.S.P., https://www.usp.org/about (last visited Jan. 31, 2023).

[183] *See* U.S. Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 321(g)(1), (j).

In 2003, Congress tasked the HHS Secretary to request the USP to develop a list of model prescription drug categories and classes for Medicare Part D prescription drug plan formularies.[184] This led to the creation of the USP Medicare Model Guidelines. The USP initially updated the Model Guidelines annually but in 2008 began to revise them every three years.

The USP Medicare Model Guidelines classify drugs into categories and classes. A category is a broad classification and is designed to include potential therapeutic agents for diseases and conditions of Medicare Part D beneficiaries.[185] A class is a more granular or detailed classification within a category, structured around types of Food and Drug Administration (FDA) approved medications and is supposed to reflect current U.S. health care practices and standards of care.[186]

In the Essential Health Benefits Final Rule from February 2013 (Final Rule 2013), HHS chose the USP Medicare Model Guidelines classification system (version 5.0) as the comparison tool to determine EHB prescription drug coverage.[187] Per the Final Rule 2013, health plans must cover at least the greater of 1) one drug in every USP therapeutic category and class or 2) the same number of drugs in each USP category and class as the state's EHB base-benchmark plan.[188]

USP Drug Classification

In 2017 USP developed a new list, the USP Drug Classification (USP DC), which purports to assist with formulary support outside of Medicare Part D; however, it uses MMG as the baseline, and then adds additional common outpatient drugs on top of that list. As a result,

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[184] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. § 1395w-104(b)(3)(C)(ii).
[185] United States Pharmacopeial Convention, *USP Medicare Model Guidelines v6.0: Development of the USP Medicare Model Guidelines v6.0*, https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines/medicare-model-guidelines-v60 (last visited Jan. 31, 2023).
[186] *Id.*
[187] *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, 78 Fed. Reg. 12,834, 12,845-46 (Feb. 25, 2013) (codified at 45 C.F.R. pt. 156). For the USP Medicare Model Guidelines version 5.0 see United States Pharmacopeial Convention, *USP Medicare Model Guidelines v6.0 & v5.0*, https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40 (last visited Jan. 31, 2023).
[188] 45 C.F.R. § 156.122(a).

many of the relics of Part D remain, specifically the exclusion of 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

USP DC Development Compared to the MMG

A subcommittee of the USP's Healthcare Safety & Quality Expert Committee is charged with developing and updating the USP DC. This committee consists of experts in the field, including academicians, practitioners, formulary experts, patient advocates, and clinicians.[189] The committee relies on stakeholder input gathered through a public comment period. Following each comment period, USP annually updates the USP DC.

In contrast, USP updates the MMGs every three years. The MMG process also includes a public comment process. However, comments submitted for both the USP DC and the MMG are not publicly available on the USP website.

Although annually updated, the USP DC does not have a separate process in evaluating new market drugs throughout the year. In other words, drugs considered for the upcoming USP DC must be available, and on the market, prior to the release of the Proposed USP DC Draft in the fall. Medications that are not still in the FDA-approval pipeline are not included, resulting in some lag time before new drugs can be included.[190]

The USP DC includes 50 categories and 172 classes with 1961 example drugs.[191] In comparison, MMG's 2020 version has 47 categories and 156 classes with 1986 example drugs. All of the current MMG classifications have been included in the USP DC.[192] The three drug categories added to the USP DC that are not included in the MMG are anti-obesity agency, infertility agents, and sexual disorder agents.[193]

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[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] United States Pharmacopeial Convention, USP Drug Classification, https://www.usp.org/health-quality-safety/usp-drug-classification-system (last visited Jan. 31, 2023).
[193] United States Pharmacopeial Convention, FAQs: USP Drug Classification System (Feb. 1, 2017), https://www.usp.org/frequently-asked-questions/usp-drug-classification-system (last visited Jan. 31, 2023).

Drugs Essential for Reproductive Health

The USP DC fails to provide categories specific to abortion or even pregnancy care, even though there are categories for SUD treatment, infertility care, sexual disorders, contraceptives, and STI treatment. USP DC has a number of categories and classes that involve hormonal agents, including an "other" class; this is the only place where mifepristone, one of two drugs used for medication abortion, is listed as an example.

Misoprostol, the other drug used for medication abortion, is included on the USP DC, but completed unrelated to its use in abortion care; misoprostol is listed under the category of gastrointestinal agents as an example of the drugs in the protectant class, as well as under the category of prostaglandins. However, mifepristone and misoprostol are only examples of drugs that could be included under those categories; prescription drug plans would be free to design formularies that exclude medication abortion drugs entirely and still be fully compliant with the proposed EHB standard of one drug per class and category.

USP DC is not the standard for contraceptive coverage in EHBs; EHBs must cover a broad range of contraceptives, as delineated by the HRSA Women's Guidelines. Nonetheless, it is worth noting that should USP DC become the standard for contraceptive coverage, it would be woefully inadequate. The FDA recognizes a minimum of 19 contraceptive methods, ten of which are prescription-only drug products, 3 of which are drug products available over-the-counter, four of which are devices (which may or may not require a prescription), and two of which are medical procedures. USP DC, on the other hand, has only three drug classes: combination oral contraceptives, progestin-only oral contraceptives, and "other" contraceptives, which is a catchall class that incorporates IUDs, rings, patches, emergency contraception, injectable contraception, and ph modulation gel. Nonoxynol-9, which is the active ingredient in the sponge and spermicide, is completely omitted.

If HHS adopts the USP DC as the EHB prescription drug standard, it must underscore for issuers that contraceptive formularies must be based on statutory requirements, FDA's Orange Book, and HRSA's Women's Guidelines.[194]

[194] DOL, HHS, Dep't of Treasury, *FAQs About Affordable Care Act Implementation (Part 54)* (July 28, 2022), https://www.cms.gov/files/document/faqs-part-54.pdf. *See also* Liz McCaman Taylor, Nat'l Health Law Prog., *Fact Sheet: State Contraceptive Equity Laws* (Dec. 2021), https://healthlaw.org/wp-content/uploads/2021/12/CE-Fact-Sheet-12082021-final.pdf.

Pediatric Prescription Drugs

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.[195] 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.[196] The USP DC does not provide for pediatric formulations of prescription drugs approved for both adults and children.

Drugs covered under Medicare Part B

In 2012, the American Hemophilia Foundation and a coalition of organizations representing people who use plasma-derived and recombinant products raised concerns that the MMG, designed for the Medicare Part D program, does not include clotting factors and other blood products which are covered under Medicare Part B.[197]

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[195] *See* NIH, 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 Jan. 31, 2023).

[196] 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.

[197] 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. *See also* Nat'l Hemophilia Found., *Re: HHS Notice of Benefit and Payment Parameters for 2022 (CMS-9914-P)* (Dec. 30, 2020), https://www.hemophilia.org/sites/default/files/document/files/A-PLUS%2012.21.12.pdf.

The USP DC includes all clotting factors (and some non-factor products) into one single class (blood products and modifiers) and one single category (blood component deficiency/replacement). The USP/DC system lumps together a wide array of products used to treat (non-interchangeably) at least seven wholly separate conditions: hemophilia A, hemophilia B, von Willebrand disease, etc.

For example, drugs to treat Hemophilia A are grouped under "Blood Products and Modifiers" with only five differentiating classes.[198] Under each class, multiple drugs treat Hemophilia A, but there are also drugs that only treat other blood diseases such as Hemophilia B and Von Willebrand disease. Thus, drug formularies may choose five different "Blood Products and Modifiers," however, they may choose drugs that do not treat Hemophilia A at all. Further, treatment of Hemophilia A may require a combination of drugs with varying ease of use.

Thus, while an incremental improvement over the MMG, the USP/DC still falls significantly short of meeting the needs of a diverse patient population that relies on plasma-derived and recombinant products. Although the USP DC attempts to classify combinations of drugs, it does not go far enough to account for the complexities of drug prescription and usage.

Public and Transparent Classification System

Quality, access, and coverage standards in publicly funded health programs should be promulgated by public entities, not private companies. In addition, standards for prescription drug formularies should be publicly available, free of charge. Prohibitively expensive paywalls prevent consumers and other stakeholders from adequately assessing health plan formularies and their compliance with the ACA's EHB standards and non-discrimination provisions. **We urge HHS to develop its own prescription drug classification standards and publications, rather than relying on those developed and published by private companies. In the interim, whatever standard classification system HHS employs (e.g., AHFS, MMG, USP DC, or something else), we urge HHS to require the drug classification to be made available to consumers and other stakeholders without charge.**

[198] Nat'l Hemophilia Found., *supra* note 197.

HHS Should Improve EHB Prescription Drug Coverage Requirements

In NHeLP's 2021 letter to HHS Secretary Becerra, and our 2022 follow up letter to CCIIO Director Montz, we documented alarming deficiencies in prescription drug coverage under the current regulatory minimums and benchmarking process.[199] We affirm herein that regardless of what drug classification system it uses, **HHS should establish robust minimum coverage standards for prescription drugs. This should include at least two drugs per class and category, and all or substantially all drugs described in 42 U.S.C. § 1395w-104(b)(3)(G)(iv); as well as all medications approved by the FDA to treat OUD and opioid overdose reversal agents.**

HHS Should Enforce EHB Cost-Sharing Protections

Insurers, through contracts with Pharmacy Benefits Managers, are increasingly adopting a practice whereby they declare certain, high-cost drugs as "non-EHB." By classifying a particular drug as covered but it is not included in an EHB category means that a patient will pay the full cost of the drug until the deductible is met, share costs with the plan (via copay or coinsurance) until the plan's annual or lifetime cap is hit, and then the patient must pay out-of-pocket for all further costs for the drug.

Health plans have justified these attempts to evade ACA cost-sharing protections by arguing that if a plan covers the minimum required drugs, additional covered drugs are not EHBs.[200] Issuers also cite to CMS guidance that states plans can "continue to impose annual and lifetime dollar limits on benefits that do not fall within the definition of EHB."[201]

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[199] *NHeLP Letter Re: Advancing Health Equity Trough EHB*, *supra* note 1; *NHeLP Letter Re: Rx and Maternity Care EHB Standards*, *supra* note 1.

[200] *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. Under 45 C.F.R. § 156.122(a), plans must cover the greater of one drug per U.S. Pharmacopeia class and category, or the state's benchmark. Note the ACA explicitly states that the regulation should not be construed as limiting a plan if it wants to provide additional benefits. 42 U.S.C. § 18022(b)(5).

[201] CMS, *Frequently Asked Questions on Essential Health Benefits Bulletin* 4 (Dec. 16, 2011), https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf.

We therefore welcome HHS' unequivocal affirmation that "plans could exceed the minimum number of drugs required to be covered and that additional drugs would still be considered EHB."[202] However, we urge HHS to take further, decisive action in reigning in these egregious violations of ACA cost sharing protections.

Compliance and enforcement of EHB protections is an important issue for health care consumers. At the 2022 Fall Meeting of the National Association of Insurance Commissioners (NAIC), consumer representatives presented on issuer declarations of "non-EHB," also characterized as "Alternative Funding Programs," in two NAIC sessions urging state and federal enforcement action.[203]

We strongly urge HHS to establish robust coverage standards for prescription drugs and other EHB categories; and to rigorously enforce those standards amid increasing issuer attempts to evade their obligations to enrollees under the law.

V. Substitution of EHB

Question: We seek comments regarding the extent to which plans have ever substituted EHB under § 156.115.

- *To the extent substitution is not widely used, how should CMS revisit current rules in future rulemaking so that consumers have access to health plans that can better address changing public health concerns or innovating in health care? Alternatively, should plans not be permitted to substitute EHB within the same EHB category?*

Substitution of benefits is another area where information of actual practices is severely lacking. While we do not think substitution is widely used, we believe it is important that states and HHS maintain updated information about plans that are actively substituting benefits. Plans are required to submit this information when applying for QHP certification so states and HHS should already own this information. **Together with the actuarial certification demonstrating that substitution of benefits is within the allowable limit, information**

[202] 87 Fed. Reg. 74100.
[203] *See* Carl Schmid, *supra* note 163. *See also* Wayne Turner, Nat'l Health Law Prog., *Federal Health Policy Update, Consumer Liaison* 110 (Dec. 12, 2022), https://content.naic.org/sites/default/files/national_meeting/Meeting%20Materials_Consumer_2022%20FNM.pdf.

about which services are being substituted and for which new services they are being substituted should be made public so that consumers are aware about the changes when selecting plans. HHS should also require states to post this information in their Marketplace websites or in some form of public outlet readily accessible for the public. In fact, all plans that substitute benefits, both in state and federally facilitated Marketplaces, should be marked as including benefits that are different from the standard benefits required under the EHB benchmark plan.

We also take this opportunity to reiterate our position that benefit substitution is not allowed by the ACA and HHS should change its policy towards it. While the ACA does not explicitly prohibit benefit substitution, nowhere does the statute mention substitution either within or between benefit categories. However, under the current regulatory policy, issuers may substitute services that certain populations (*e.g*., individuals with chronic conditions) need and replace them with actuarially equivalent services, which may be less costly and more likely to attract healthier populations. If substitution was widely adopted by plans, it will likely result in coverage gaps and higher out-of-pocket costs for consumers in need of services that are substituted and not covered by the issuer.

Further, we do not think substitution is an appropriate solution to public health emergencies. Health plans have traditionally refused to adjust their coverage to address a public health emergency. Rather, in an effort to reduce costs, plans typically seek to limit access to services that, because of public health emergencies, are in high demand. For example, plans have not been effective in closing gaps in access to SUD treatment as a tool to address the overdose epidemic. Many plans still refuse to cover all three FDA-approved MAT medications unless required to do so by states or the federal government. And when they are required to cover these services, they have resorted to utilization controls, such as prior authorization, to reduce service utilization and, thus, costs to the plan. Similarly, without federal intervention, we doubt that plans would have made widely available tests and treatment for COVID-19 at the start of the pandemic.

Instead of leaving it to health plans, federal regulators are best positioned to respond to emergencies and, in fact, we believe the ACA provided the tools for doing so. HHS has full authority to review and update EHB as needed when a public health emergency hits and this is precisely what the ACA intended. We urge HHS to prohibit benefit substitution both within and between EHB categories, and to establish a standard and periodical review and update process that takes into account ongoing and developing public health emergencies.

Conclusion

We have included citations and direct links to research and other materials. We request that the full text of material cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these citations part of the record as we have requested, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

Thank you for your attention to our comments. If you have any questions or need any further information, please contact Héctor Hernández-Delgado (hernandez-delgado@healthlaw.org) or Wayne Turner (turner@healthlaw.org).

Sincerely,

Héctor Hernández-Delgado
Senior Attorney