December 6, 2021

The Hon. Xavier Becerra, Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: Advancing Health Equity Through Essential Health Benefits

Dear Secretary Becerra:

The National Health Law Program (NHeLP) has worked to improve health care access and quality through education, advocacy, and litigation on behalf of low-income and underserved individuals for over fifty years. We share 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."[1] NHeLP also shares the administration's vision to "advance equity for all, including people of color and others who have been historically underserved."[2] The Administration's commitment to these issues aligns with NHeLP's Equity Stance.

To that end, we have identified numerous opportunities under Essential Health Benefits (EHB) provision of the Affordable Care Act (ACA) where the Department of Health and Human Services (HHS) can, through the regulatory process, close coverage gaps, reduce disparities, and advance health equity. Congress gave HHS considerable authority to define and implement EHBs. We urge HHS to use that authority to improve and strengthen EHB coverage.[3] In doing so, the Biden-Harris

administration can advance health equity through the existing framework of the ACA.

I. Improving EHB Coverage Standards

The ACA requires the Secretary to define EHB and does not allow the delegation of that authority to states or issuers.[4] However, instead of establishing a federal EHB standard, HHS pursued a state benchmarking process, which has resulted in inconsistent and inadequate coverage.[5] Varying EHB standards have meant that individuals have different benefits depending on where they live, rather than on their medical needs. A growing body of evidence shows that under EHB benchmarking, health plans often fail to meet the needs of underserved populations, including persons with disabilities and chronic illness, as well as Black, Indigenous, and other people of color (BIPOC).

We urge HHS to establish robust federal definitions in all ten EHB categories, and allow states to build upon a federal minimum.[6] That floor must represent the minimum package of benefits that individuals need to meet all of their health care needs. Regional or local considerations, by states and/or plans, should be relevant to decisions about providing *additional* coverage. The federal EHB standard should set a strong national floor, but not a ceiling. States and plans can be free to expand benefits packages to improve upon the national standard or take into account local health needs. In the interim, HHS should rely on benchmarking while

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[1] 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.
[2] 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.
[3] Health plans subject to EHB include plans sold through the ACA Marketplaces, non-grandfathered individual and small group plans, as well as Medicaid Alternative Benefit Plans (ABPs). See 42 U.S.C. § 300gg–6, 42 U.S.C. § 18021(a)(1)(B), 42 U.S.C. § 1396u-7(b)(5).
[4] 42 U.S.C. § 18022(b)(1).
[5] In 2012, NHeLP warned that EHB benchmarking would lead to inconsistent coverage. *See*, NHeLP Letter to Kathleen Sebelius, Dept. of Health & Human Srvs., *Re: Essential Health Benefits Bulletin, Center for Consumer Information and Insurance Oversight (CCIIO)* (Jan. 31, 2012); *See also* NHeLP Letter to Kevin Counihan, Ctr. for Consumer Information and Insurance Oversight, *Re: Proposed 2017 Essential Health Benefits Benchmark Plans* (Sept. 30, 2015), https://healthlaw.org/resource/nhelp-comments-proposed-2017-essential-health-benefits-benchmark-plans/.
[6] HHS has already established minimum definitions in two EHB categories – prescription drugs and habilitative and rehabilitative services. *See* 45 C.F.R. § 156.122; § 156.115(a)(5).

transitioning to federal coverage standards, and phase in enhanced coverage standards to address unmet health needs.

a. Prescription drugs

In a 2013 rulemaking, HHS established a federal minimum standard for EHB prescription drug coverage – the greater of one drug per U.S. Pharmacopeia (USP) class and category, or the number in a state's benchmark plan.[7] That standard has proven inadequate to meet the needs of highly vulnerable patient populations that rely on prescription drugs, and should be improved.

Plans can meet the minimum EHB coverage standard, but not cover the most commonly prescribed medications used to treat certain conditions. For example, in 2014, HIV advocates raised concerns that Qualified Health Plans (QHPs) failed to cover single tablet therapy for HIV.[8] Single tablet therapy is a combination of antiretroviral drugs in a single tablet and has become the standard of care in HIV treatment because it supports adherence and helps prevent drug resistance.[9] A subsequent study found "wide variation in coverage of EHBs across plans," and that benchmark prescription drug coverage does not guarantee coverage of the most appropriate anti-retroviral therapy.[10]

We recognize and appreciate that HHS identified the failure to provide single tablet therapy as a "potentially discriminatory practice" in subregulatory guidance.[11] However, to fully address

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[7] U.S. Dept. of Health & Human Srvs., *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule*, 78 Fed. Reg. 12834 - 12872 (Feb. 25, 2013), https://www.govinfo.gov/content/pkg/FR-2013-02-25/pdf/2013-04084.pdf, *codified at* 45 C.F.R. § 156.122.

[8] *See, e.g.,* HIV Health Care Access Working Group, Comments on CMS Notice of Payment and Benefit Parameters for 2016 (Dec. 22, 2014) at 2, https://www.regulations.gov/document?D=CMS-2014-0152-0144.

[9] U.S. Dept. Health & Human Srvs., *Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents* (last updated Aug. 16, 2021), https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf.

[10] Lauren Lipira, et al., *Evaluating the Impact of the Affordable Care Act on HIV Care, Outcomes, Prevention, and Disparities: A Critical Research Agenda*, 28 J. HEALTH CARE FOR POOR & UNDERSERVED 1256 (2017), https://muse.jhu.edu/article/677348/pdf.

[11] See, *e.g.*, Ctrs. Medicare & Medicaid Servs, *Final 2016 Letter to Issuers in the Federally-Facilitated Marketplace* 37-38 (Feb. 20, 2015); U.S. Dept. Health & Human Srvs., *Notice of Benefit and Payment*

inadequate prescription drug coverage and access, HHS should improve the current EHB coverage standard.

In addition to antiretrovirals used to treat HIV, anticonvulsants are another example of a protected drug class that greatly benefits patients. Like HIV, treatment for persons with epilepsy is highly individualized, and finding the most appropriate drug therapy requires access to the full range of anti-seizure medications. Once an appropriate regimen has been determined, it can be very destabilizing to switch to any alternative regimen. Studies have demonstrated that people with epilepsy are at greater risk of seizure after a switch. In one study, seizure-free individuals who switched their drug had a 16.7% rate of seizure recurrence at six months, compared to 2.8% among people remaining on the same drug.[12]

HHS should require EHB plans to cover a minimum of two drugs per USP class and category, following Medicare Part D, and include the Medicare Part D requirement to cover "all or substantially all" of the drugs in six protected classes of drugs which are critical to vulnerable populations.[13] Protected classes were explicitly included in Part D "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans."[14] Requiring EHB plans to "cover substantially all" the Part D protected classes would ensure that highly vulnerable patient populations will have full access to medically necessary treatment.

We also urge HHS to not only adopt, but also build upon the Medicare Part D standard for prescription drug coverage in EHB plans. We recommend the addition of drugs used for treatment of opioid use disorders (OUD) and opioid overdose reversal agents to the list of protected classes, and require EHB plans to cover substantially all of these live-saving

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Parameters for 2016 Final Rule, 80 Fed. Reg. 10822 (Feb. 27, 2015), https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.

[12] Finamore, J.M., et al., *Seizure outcome after switching antiepileptic drugs: A matched, prospective study*, EPILEPSIA 57(8), 1294-300 (2016), https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13435.

[13] During implementation of the Patient Improvement and Medicare Modernization Act (MMA) in 2003, CMS issued sub-regulatory guidance directing prescription drug plans to cover "all or substantially all" medications within six classes and categories that the agency identified, including: anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, immunosuppressants. In 2008, Congress codified Medicare's six protected classes policy as part of the Medicare Improvement and Patient Protection Act (MIPPA). In the ACA, Congress codified by name the existing six protected classes and required coverage of all medications.

[14] Medicare Prescription Drug Benefit Manual Chapter 6, § 30.2.5.

medications. Studies show there are significant gaps remain in accessing these medications during the ongoing opioid and overdose epidemics. A 2019 study of state benchmark plan coverage of opioid use disorder treatments and services found that approximately two-fifths of benchmark plans do not cover the opioid overdose reversal agent, naloxone, despite the fact that the current prescription drug standard implicitly requires coverage of this medication. Another study, from 2017, found that the vast majority of state benchmark plans are either silent or explicitly exclude methadone for opioid use disorder treatment.[15]

As of today, the FDA has approved three medications to treat opioid use disorders: Buprenorphine, Methadone, and Naltrexone. While these medications, particularly Buprenorphine and Methadone, have been proven effective in reducing the effects of OUDs and overdose deaths, most individuals who need them are currently not accessing what is considered the gold standard of SUD care, in part because plans are currently not required to cover all medications. Pursuant to the current EHB prescription drug standard, states must require coverage of at least Buprenorphine or Naltrexone. This means that unless the state selects a benchmark plan that covers both medications, plans can cover Naltrexone and refuse to cover the more effective Buprenorphine, leaving individuals with OUD at risk of relapse and overdose.[16] Besides mandating coverage for all of these medications, HHS should mandate that coverage for FDA-approved medications for OUD and for overdose reversal agents not be subject to limitations such as prior authorization, step therapy requirements, and concurrent counseling requirements. Similarly, HHS should mandate coverage of any FDA-approved overdose reversal medication, without limitations, as part of the prescription drug or MH/SUD EHB requirement.

In sum, HHS should expand the EHB prescription drug standard to a minimum of two drugs per USP class and category, and require coverage of substantially all medications in the Medicare six protected classes, and all FDA-approved drugs used in the treatment of OUD.

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[15] Stacey A. Tovino, State Benchmark Plan Coverage of Opioid Use Disorder Treatment and Services: Trends and Limitations, 70 S.C.L. REV. 763 (2019).

[16] We understand that coverage of methadone for OUD typically falls within the EHB category of mental health and substance use disorder services and not under the prescription drug category. As long as this system is maintained, HHS should require coverage of at least Buprenorphine and Naloxone as minimum requirements to meet the prescription drug coverage standard, and should require coverage of methadone maintenance therapy in opioid treatment programs as a minimum standard for the MH/SUD EHB category.

b. Habilitative and rehabilitative services

HHS helped address the gap in coverage when it adopted a minimum federal definition for habilitative services and devices, and requiring plans to cover habilitative services on par with rehabilitative services.[17] Unfortunately, individuals with diverse types of disabilities still struggle to access medically necessary services and devices. We suggest several changes below to address two areas where individuals still face significant gaps in coverage: Durable Medical Equipment (DME) and Medical Foods.

1) Durable Medical Equipment

We have received multiple reports from advocates in various states where individuals with disabilities cannot access DMEs such as mobility aids (including wheelchairs), oxygen supplies (such as continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPap machines), and hearing aid devices and fitting services. For individuals with certain diagnosis, these services and devices help individuals keep, learn, get back, or improve skills and functioning for daily living. Without health insurance coverage, these devices would be cost prohibitive for many individuals who need them. In addition, even when the services and devices are covered, they are often subject to high cost-sharing requirements that create further barriers to access.

HHS should clarify coverage of rehabilitative and habilitative services and require a minimum level of coverage of DME. All EHB plans should provide coverage for commonly used DME, including hearing aid services and devices, all types of wheelchairs, and CPAP and BiPap machines when these devices are found to be medically necessary. In addition, HHS should encourage states and plans to exempt coverage of all DME from cost-sharing, including deductibles, copayments, and coinsurance.

2) Medical Foods

In addition to DME, we urge HHS to amend the definition of habilitative services 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

[17] 45 C.F.R. § 156.115(a)(5).

disorders, and other conditions.[18] 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, may 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 under durable medical equipment. Excludes all other medical foods.
- Mississippi: Makes no mention of any coverage for medical foods.
- North Carolina: Explicitly excludes all "formulas or special foods of any kind."[19]

While medical foods may be covered under habilitative services in most instances, we believe coverage of these services should be broad to include all necessary services, including those that may fall outside of the rehabilitative and habilitative services category. (See discussion in Section II below on reviewing and expanding EHB). 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

[18] 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).
[19] Ctr. for Consumer Information and Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans*, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.

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 rehabilitative and habilitative services 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.[20] Expanding the rehabilitative and habilitative services 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.

c. Maternity care

While the ACA mandated maternity care as an EHB, pregnant individuals still struggle to access adequate care. Rates of maternal death are on the rise, in contrast to virtually every other similarly economically situated country. Women of color, especially Black women and those with lower incomes, are at the highest risk of poor birth outcomes in the United States.[21] However, the EHB benchmarking system has led to inconsistent and inadequate coverage in plans subject to EHB. A 2021 review found wide variation among states' EHB benchmark plans coverage of maternity care, including: limits placed on the number of prenatal and labor and delivery services covered, exclusion of coverage for individuals claimed as dependents, provision of postpartum and lactation services, coverage of breastfeeding support and supplies, coverage of midwives and doula support or restrictions applied, and coverage of home births and birth centers.[22]

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[20] Brault, Matthew, *Americans With Disabilities: 2005, Current Population Reports*, P70-117, U.S. Census Bureau, Washington, DC, 2008; Bowen, M., & González, H. (2008). Racial/Ethnic Differences in the Relationship Between the Use of Health Care Services and Functional Disability: The Health and Retirement Study (1992-2004); The Gerontologist, 48(5), 659-67.

[21] Julia Chinyere Oparah et al., Battling Over Birth: Black Women and the Maternal Health Care Crisis (Dec. 2, 2017).

[22] Nora Ellmann & Jamille Fields Allsbrook, *States' Essential Health Benefits Coverage Could Advance Maternal Health Equity*, Ctr. for American Progress (Apr. 30, 2021),

HHS has the opportunity to establish a better standard for what should be included in this EHB category. HHS should adopt the recent guidelines developed by the American Academy of Pediatrics Committee on Fetus and Newborn as well as the American College of Obstetricians and Gynecologist Committee on Obstetric Practice.[23] The guidelines recommended a minimum number of prenatal and postpartum appointments for uncomplicated pregnancies: every four weeks for the first 28 weeks of gestation, every two weeks until 36 weeks of gestation, and weekly thereafter. They also recommended that prenatal services are covered irrespective of pregnancy outcomes, including miscarriage, delivery, and abortions.[24] These recommendations should be featured in HHS policy.

Research demonstrates that access to midwifery care, home births, and birthing at birth centers results in positive outcomes to the birthing person and their child.[25] The COVID-19 public health emergency has also propelled an increased interest in home births.[26] Pregnant people and their families, wary of seeking care in hospital and clinic settings where they may be exposed to COVID-19, are opting for ways to seek prenatal care and support closer to home. HHS should require plans cover every type of qualified midwife, including certified nurse midwives as well as certified professional midwives, without the requirement for physician supervision.

Moreover, maternity care should include full spectrum doula care. Doulas are individuals trained to provide non-clinical emotional, physical and informational support for people before, during, and after labor and birth. Doula care is among the most promising approaches to combating disparities in maternal health. Pregnant individuals receiving doula care have been found to have improved health outcomes for both themselves and their infants, including higher breastfeeding initiation rates, fewer low-birth weight babies, and lower rates of cesarean

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https://www.americanprogress.org/issues/women/news/2021/04/30/498751/states-essential-health-benefits-coverage-advance-maternal-health-equity/.

[23] Am. Academy of Pediatrics & Am. College of Obstetricians & Gynecologists, *Guidelines for Perinatal Care* (8th Edition), https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.

[24] *Id.*

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

[26] *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/.

sections.[27] Doulas can also help reduce the impacts of racism and racial bias in health care on pregnant women of color by providing individually tailored, culturally appropriate, and patient centered care and advocacy.[28]

At minimum, plans should cover three prenatal doula visits and three postpartum doula visits. Coverage must be inclusive of the wide variety of doula training models, traditions, and practices, including those by community-based doula groups and by doula trainers of color.

We urge HHS to align EHB maternity coverage requirements with medical guidelines issued by American Academy of Pediatrics Committee on Fetus and Newborn and the American College of Obstetricians and Gynecologist Committee on Obstetric Practice, and establish minimum coverage requirements for a range of midwife services and doula care.

d. Pediatric services

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.[29]

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 disabilities."[30] Researchers found specific pediatric exclusions within certain treatment categories associated with pediatric developmental and mental health

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[27] *See* Asteir Bey et al., *Advancing Birth Justice: Community-Based Doula Models as a Standard of Care for Ending Racial Disparities* (Mar. 25, 2019), https://everymothercounts.org/wp-content/uploads/2019/03/Advancing-Birth-Justice-CBD-Models-as-Std-of-Care-3-25-19.pdf.

[28] *See* Amy Chen & Alexis Robles-Fradet, National Health Law Program, *Building A Successful Program for Medi-Cal Coverage For Doula Care: Findings From A Survey of Doulas in California* (May 21, 2020), https://healthlaw.org/resource/doulareport/.

[29] *See* Wakely Consulting Grp., *Comparison of Benefits and Cost Sharing in Children's Health Insurance Programs to Qualified Health Plans* (July 2014), http://www.wakely.com/wp-content/uploads/2014/07/FINAL-CHIP-vs-QHP-Cost-Sharing-and-Benefits-Comparison-First-Focus-July-2014-.pdf.

[30] Grace AM, et al., *The ACA's pediatric essential health benefit has resulted in a state-by-state patchwork of coverage with exclusions*, HEALTH AFFAIRS (Dec. 2014), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0743.

conditions, including services for children with learning disabilities, speech therapy, and services for children with developmental disabilities and delays.[31]

We underscore the importance of offering comprehensive pediatric services, coverage of habilitative services and devices that meet children's developmental needs, and access to a full range of pediatric oral and vision services.[32] The 2017 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."[33]

The American Academy of Pediatrics observed wide variation among benchmark plans in coverage of pediatric services and recommended:

> The Centers for Medicare & Medicaid Services should implement its regulatory authority to update its standards for essential health benefits, as defined in the ACA, in the 2 categories of mental and behavioral health services and pediatric services. These essential health benefits should be consistent with the full scope of benefits outlined in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition* (including health supervision visits, nationally recommended immunizations, screening for high-risk conditions, and adequate counseling and treatment of conditions related to sexual and reproductive health, mental and behavioral health, and substance use disorder). In this way, all (adolescents and young adults)

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[31] *Id*.

[32] *See* comment letter on the proposed 2017 EHB benchmark plans submitted by the Children's Hospital Association on behalf of a number of organizations for additional observations and recommendations regarding coverage of pediatric services, Children's Hospital Association, et al., to Letter to Kevin Counihan, Ctr. for Consumer Information and Insurance Oversight, Re: Proposed 2017 Essential Health Benefits Benchmark Plans (Sept. 30, 2015), https://www.childrenshospitals.org/-/media/Files/CHA/Main/Issues_and_Advocacy/Key_Issues/Exchanges_and_Private_Coverage/Letters_and_Testimony/2015/Comments_on_Pediatric_Coverage_2017_EHB_benchmarks09302015.pdf.

[33] 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 (2019).

AYAs can access the full range of services needed during this developmentally critical period to secure optimal physical and mental health as they enter middle adulthood.[34]

Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is the gold standard for pediatric services.[35] We recommend that HHS establish a federal minimum definition for EHB pediatric services based on Medicaid's EPSDT benefit standard.

e. Mental Health and Substance Use Disorder Services

Before the ACA, most health insurance plans were not required to include coverage for mental health (MH) and substance use disorder (SUD) services, despite the outstanding need for them. 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. MH/SUD access issues are underscored by the fact that the vast majority of individuals with these conditions are currently not receiving treatment. The lack of access to services is exacerbated by the continuous lack of enforcement of and guidance about federal parity requirements, as even when plans do cover MH/SUD services, they have continued to impose limitations that create additional barriers to care.

In 2020, researchers published a comprehensive study of EHB benefits provided under the category for mental health and substance use disorder 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."[36]

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[34] Arik V. Marcell et al., *Targeted Reforms in Health Care Financing to Improve the Care of Adolescents and Young Adults*, PEDIATRICS (2018), https://pediatrics.aappublications.org/content/142/6/e20182998.
[35] *See* Children's Defense 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.
[36] 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/.

One of the ways plans currently circumvent requirements to cover MH/SUD services is 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.[37] 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.[38] 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.

We firmly believe plans must provide coverage for all services deemed medically necessary for treating any MH/SUD condition. Nonetheless, there are several essential services we think HHS should explicitly require all plans to cover for compliance with the EHB requirement to cover MH/SUD services. Federal regulations should specify that EHB plans cover crisis intervention services, intensive care coordination, and intensive community-based services such as Assertive Community Treatment (ACT). These services are rarely covered by marketplace plans, yet 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 residential settings for patients with MH/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*.[39]

In addition, HHS should clarify that in order to meet the minimum standard for MH/SUD coverage, all plans must cover Methadone Maintenance Therapy (MMT) for OUD provided in opioid treatment programs (OTPs). As explained above, along with Buprenorphine, Methadone is one of the most effective medications for treatment of OUD. Because under federal law Methadone for OUD can only be administered or prescribed in OTPs, the medication typically

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[37] See *Wit v. United Behavioral Health*, Brief amicus curiae of Nat'l Health Law Prog., et al., 26 May 2021, https://healthlaw.org/resource/wit-v-united-behavioral-health-care-u-s-court-of-appeals-ninth-circuit/.
[38] *Wit v. United Behavioral Health*, 317 F.R.D. 106 (N.D. Cal. 2016).
[39] *Olmstead v. L. C.*, 527 U.S. 581 (1999).

falls outside of the EHB prescription drug standard as Methadone is not part of the USP category of opioid treatment medications. This means that, since most base benchmark plans do not cover Methadone for OUD, most health plans are only required to cover the medication for pain treatment. This has resulted in significant gaps in access to this life-saving medication for individuals with OUD and this gap will continue unless HHS explicitly requires coverage of MMT in OTPs.[40]

Beyond the requirement to cover specific services, plans should be required to ensure that enrollees have access to the whole continuum of MH/SUD care. For mental health, this means that plans must address the significant gaps that remain in community-based levels of care and must ensure that individuals can access the services they need in their communities. For SUD, plans should be required to cover all services under the American Society of Addiction Medicine (ASAM) criteria and must ensure that providers are correctly utilizing the ASAM criteria to determine appropriate levels of care. Misapplication of placement criteria and lack of SUD services available in the community sometimes leads to increased utilization of inpatient and residential SUD services as the only vehicle for individuals to access life-saving care. Because of the risk of institutionalization, the solution to the lack of providers to treat both MH and SUD should be to ensure that plans maintain adequate networks of community-based providers in order to ensure proper coverage of all levels of care.

Mental health and SUD services are considerably underutilized by BIPOC communities, LGBTQ+ individuals, and other individuals of non-dominant identities, underscoring significant gaps in access to effective services.[41] This indicates that updating EHB requirements to improve access to important MH/SUD services is key to addressing health disparities and HHS should use EHB as a vehicle to achieve behavioral health equity.

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[40] *See* Lindsey Vuolo, *The Federal Government Needs to Take Stronger Action to Prevent Discriminatory Coverage of Methadone*, HEALTH AFFAIRS (April 2019), https://www.healthaffairs.org/do/10.1377/hblog20190418.164447/full/.

[41] *See* SAMHSA, 2019 National Survey of Drug Use and Health (NSDUH) Releases, https://www.samhsa.gov/data/release/2019-national-survey-drug-use-and-health-nsduh-releases (last visited Sept. 20, 2021); SAMHSA, *Racial/Ethnic Differences in Mental Health Service Use among Adults* (July 2015), https://store.samhsa.gov/product/Racial-Ethnic-Differences-in-Mental-Health-Service-Use-among-Adults/sma15-4906; SAMHSA, *National Survey on Drug Use and Health: Lesbian,, Gay, & Bisexual (LGB) Adults* (November 18, 2020), https://www.samhsa.gov/data/report/2019-nsduh-lesbian-gay-bisexual-lgb-adults.

We urge HHS to address the barriers to MH/SUD care we have outlined by amending EHB regulations in several ways. First, HHS should establish a definition of MH/SUD medical necessity criteria that plans must adopt in order to comply with the requirement to cover MH/SUD services. This definition should incorporate the court findings in *Wit* and specify that MH/SUD medical necessity criteria should align with accepted MH/SUD standards of care. In addition, HHS should require all plans to cover, at a minimum, crisis intervention services, intensive care coordination, and intensive community-based services such as ACT. Finally, federal EHB regulations should require plans to have sufficient number of community-based providers to ensure appropriate care in the entire coverage area.

II. HHS should establish a public process to review and update EHB

The ACA authorizes HHS to update and expand EHB administratively, addressing coverage gaps without the need for congressional action.[42] The ACA also requires HHS to periodically review EHB and report to Congress and the public an assessment of whether:

(1) enrollees are experiencing barriers to needed services,
(2) services should be modified or updated to account for changes in medical evidence or scientific advancement,
(3) access gaps must be addressed, and
(4) existing benefits need to be expanded or reduced and the impact on cost.[43]

To our knowledge, HHS has not conducted such a review and submitted a report to Congress to date. We believe the time is now and that such a review would form the basis for the needed changes included herein.

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

[42] 42 U.S.C. § 18022 (b)(4)(H).
[43] 42 U.S.C. § 18022 (b)(4)(G).

a. Data collection

HHS should collect and make publicly available issuer data on denials of coverage 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. HHS should establish a system of regular, standardized surveys 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.[44] HHS should also use these surveys to collect demographic information in order to disaggregate data by race, ethnicity, sexual orientation, gender identity, disability, and other important factors that contribute to health disparities.

Current and innovative survey and reporting methods and designs should be utilized to ensure that information received is based on sound protocols and guidelines. HHS should test surveys with a variety of audiences, including low-income, low literacy, Limited English Proficient individuals, people with disabilities, and underserved 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 surveys. 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.

b. Meaningful stakeholder engagement

HHS should create an independent advisory council to assist in reviewing and updating EHBs. Patient and consumer representatives should be adequately represented on the council. There should be flexibility available to HHS and the advisory council to make recommendations as to how benefits can be modified to address identified gaps in access. Further, the council should

[44] 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 used 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), https://www.opm.gov/policy-data-oversight/data-analysis-documentation/employee-surveys/2019-federal-employee-benefits-survey-report.pdf.

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, LGBTQ+ persons, and other underrepresented communities.

In sum, HHS's EHB review and updating process should be consumer-focused and data-driven to identify and address EHB coverage gaps and close health disparities.

III. Conclusion

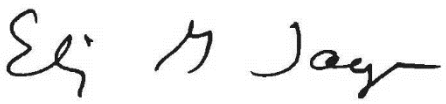
We recognize that sudden, sweeping changes to EHB requirements could affect market stability. We therefore recommend continued reliance on the benchmarking approach on a transitional basis, phasing in more robust federal coverage standards. Some EHB categories are more conducive for immediate improvement. For example, we believe HHS could enhance the current EHB federal standard for prescription drug coverage with minimum disruption, as part of the upcoming Notice of Benefit and Payment Parameters rulemaking.

HHS should embark upon the EHB review, updating, and coverage enhancements without delay, and with a lens focusing on health equity. As the COVID-19 pandemic has laid bare, the U.S. health care system has long standing and endemic inequities. The current EHB benchmarking system only furthers those inequities by basing coverage standards on commercial plans whose business model is founded on the denial of care. We believe the Biden-Harris administration is well-positioned to reverse of health care inequity by building upon the ACA and truly building back better. Moreover, the ACA's EHB provision will play an even bigger role in ensuring access to comprehensive health care with the potential enactment of the Build Back Better Act (BBB). If BBB becomes law, individuals who would be eligible for Medicaid in non-expansion states would be able to access coverage through the Marketplace, and individuals who were previously ineligible for premium tax credits will have the opportunity to enroll in subsidized insurance plans. It is thus imperative that the Administration ensures Marketplace coverage meets the needs of all current and newly eligible enrollees.

We would be glad to discuss these matters further and look forward to working with administration to end health disparities and advance health equity. Please feel free to contact

our EHB team – Héctor Hernández-Delgado at hernandez-delgado@healthlaw.org; or Wayne Turner at turner@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
Executive Director

Cc:

- Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
- Dr. Ellen Montz, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight