across income levels, sex, and racial groups.[76] In 2022, about 64% of adults ages 18 and over had a dental exam or cleaning in the past year.[77] Even when considering the effects of COVID-19 in dental care utilization among adults between 2020 and 2023, there has not been an increase to the rate of dental care utilization in 2019.[78] Previous research also indicates that income and health insurance status are important predictors of unmet dental needs that result in losing teeth and gum disease.[79] This research demonstrated that unmet dental needs are effected by the oral health care policies in their state. The researchers indicate that improvements to state and federal oral health program could greatly improve oral health.[80]

b. Oral health during pregnancy

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

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[76] Ctrs. for Disease Control and Prevention, *supra* note 63.
[77] Jeannine S. Schiller & Tina Norris, Nat'l Ctr. for Health Statistics, *Early Release of Selected Estimates Based on Data From the 2022 National Health Interview Survey* (2022), https://www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease202304.pdf.
[78] Nat'l Ctr. for Health Statistics, *Percentage of having a dental exam or cleaning in the past 12 months for adults aged 18 and over, United States, 2019–2022* National Health Interview Survey, Generated interactively: Dec 15 2023 from https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html.
[79] D.J. Gaskin et al., *Predictors of Unmet Dental Health Needs in US Adults in 2018: A Cross-Sectional Analysis*, 7 JDR CLINICAL & TRANSLATIONAL RESEARCH 398–406 (2022), https://journals.sagepub.com/doi/10.1177/23800844211035669.
[80] *Id.* J.S. Feine, *Oral Health Care Access, Inequity, and Inequality*, 7 JDR CLIN TRANS RES. 332–333 (2022).
[81] Am. Dental Assoc., Pregnancy (2021), https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/pregnancy.
[82] Shailesh M. Gondivkar, Amol Gadbail, & Revant Chole, *Oral pregnancy tumor*, 1 CONTEMP CLIN DENT. 190–192 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3220110/.

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

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

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

c. Racial disparities

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

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[83] Ctrs. for Disease Control and Prevention, *Pregnancy and Oral Health*, https://www.cdc.gov/oralhealth/publications/features/pregnancy-and-oral-health.html (last visited Dec. 20, 2023). These comments will occasionally use the terms "women" or "woman" as well as other gendered language where the research data or laws cited uses those specific terms. We recognize that people of different genders, gender identities, and expressions can become pregnant and need access to care. As such, we have tried to otherwise limit our use of gendered language where possible.
[84] Susan Lieff et al., *The oral conditions and pregnancy study: periodontal status of a cohort of pregnant women*, 75 *J Periodontol*, 116–126 (2004), https://pubmed.ncbi.nlm.nih.gov/15025223/.
[85] Ctrs. for Disease Control and Prevention, *supra* note 63.
[86] L.A. Daalderop et al., *Periodontal Disease and Pregnancy Outcomes: Overview of Systematic* Reviews, 3 JDR CLIN TRANS RES. 10–27 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6191679/.
[87] *Id.*
[88] *Id.*

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

d. Cost of dental care

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

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

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[89] L.N. Borrell & D.R. Williams, *Racism and oral health equity in the United States: Identifying its effects and providing future directions*, 82 J PUBLIC HEALTH DENT. 8–11 (2022).
[90] G.L. Wehby, W. Lyu, D. Shane, *Racial And Ethnic Disparities In Dental Services Use Declined After Medicaid Adult Dental Coverage Expansions*, 41 HEALTH AFF. 44–52 (2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01191.
[91] Niodita Gupta & Marko Vujicic, Am. Dental Assoc., Health Policy Inst., *Barriers to dental care are financial among adults of all income levels* (2019), https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/hpi/hpibrief_0419_1.pdf.
[92] *Id.*
[93] Marko Vujicic, Thomas Buchmueller, & Rachel Klein, *Dental Care Presents the Highest Level of Financial Barriers, Compared to Other Types of Health Care Services*, 35 HEALTH AFF. 2176–2182 (2016), https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0800.

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

e. Adult dental care effects on children

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

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

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[94] *Id.*
[95] J. Shahangian, *Brushing for Two: How Your Oral Health Affects Baby*, https://www.healthychildren.org/English/ages-stages/prenatal/Pages/Brushing-for-Two-How-Your-Oral-Health-Effects-Baby.aspx (last visited Dec. 20, 2022).
[96] *Id.*
[97] Bruce A. Dye et al., *Assessing the relationship between children's oral health status and that of their mothers*, 142 J AM DENT ASSOC. 173–183 (2011), https://jada.ada.org/article/S0002-8177(14)61498-7/fulltext.
[98] Ctrs. for Disease Control and Prevention, *supra* note 63.
[99] D.M. Shearer et al., *Maternal oral health predicts their children's caries experience in* adulthood, 90 J DENT RES. 672–677 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3144114/.
[100] Jana Olak et al., *The influence of mothers' oral health behavior and perception thereof on the dental health of their* children, 9 EPMA J. 187–193 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5972135/.

f. Coverage of adult dental care

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

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

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

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

[101] Gary Claxton et al., Kaiser Fam. Found., *Employer Health Benefits Survey 2023 Annual Survey* 55 (2023), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf.
[102] 88 Fed. Reg. 82598.
[103] 45 C.F.R. § 156.111(c).
[104] Abraham D. Flaxman et al., *Prevalence of Visual Acuity Loss or Blindness in the US: A Bayesian Meta-analysis*, 139 JAMA OPHTHALMOLOGY 717 (2021).
[105] *Id.*
[106] Angela R. Elam et al., *Disparities in Vision Health and Eye Care*, 129 OPHTHALMOLOGY 89 (2022).

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

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

Along with diabetic retinopathy, glaucoma is also one of the leading causes of irreversible blindness in the U.S.[113] By 2050, studies project that the three million people currently living with the disease will increase to 6.3 million.[114] Similarly, cataracts in one or both eyes can occur at any age and will also increase in number as the population increases in 2050.[115] Other causes of vision impairment are primarily age-related eye diseases, such as diabetic retinopathy, glaucoma, age-related macular degeneration, cataracts; and other causes include amblyopia and strabismus.[116]

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

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[107] Diana E. Fisher et al., *Visual Impairment in White, Chinese, Black, and Hispanic Participants from the Multi-Ethnic Study of Atherosclerosis Cohort*. 22 OPHTHALMIC EPIDEMIOLOGY 321 (2015).
[108] Elam, *supra* note 106.
[109] Rohit Varma et al., *Visual Impairment and Blindness in Adults in the United States: Demographic and Geographic Variations from 2015 to 2050*, 134 JAMA OPHTHALMOLOGY 802 (2016).
[110] Flaxman, *supra* note 104.
[111] *Id.*
[112] *Id.*; Elam, *supra* note 106.
[113] Ctrs. for Disease Control and Prevention, *Vision Health Initiative (VHI): Common Eye Disorders and Diseases* (2023), (last visited Dec. 17, 2023), https://www.cdc.gov/visionhealth/basics/ced/index.html#diabetic_retinopathy.
[114] Varma, *supra* note 109.
[115] *Id.*
[116] Ctrs. for Disease Control and Prevention, *supra* note 63.

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

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

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

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

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[117] David B. Rein et al., *The economic burden of major adult visual disorders in the United States*, 124 JAMA OPHTHALMOLOGY 1754 (2006).
[118] Brad Wong et al., *The case for investment in eye health: systematic review and economic modelling analysis*, 101 BULLETIN WORLD HEALTH ORGANIZATION 786 (2023).
[119] Elam, *supra* note 106.
[120] *Id.*
[121] Peter Shin and Brad Finnegan, *Assessing the need for on-site eye care professionals in community health centers*, *in* 22 HEALTH POLICY AND MANAGEMENT ISSUE BRIEFS 16–18 (2009).
[122] Mapa Piyasena et al., *Systematic review on barriers and enablers for access to diabetic retinopathy screening services in different income settings*, 14 PLOS ONE e0198979 (2009).

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

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

As with the other prohibitions in §156.115(d), the statutory language of the ACA does not mandate any express exclusion of "excepted benefits" from EHB. Nevertheless, in addition to EHB nondiscrimination requirements, HHS and states, as well as other covered entities must comply with federal anti-discrimination mandates, including § 504 of the Rehabilitation Act of 1973, as incorporated by § 1557.[124] Specifically, covered entities under § 1557 are prohibited from providing health programs and services that are more segregated than are appropriate to the needs of people with disabilities, and from employing coverage policies, benefit design, coverage decisions, and other criteria and methods of administration that would do the same.[125] If a state were to include institutional services such as nursing facility care as an EHB, but exclude home and

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

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

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

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

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

§ 156.122 – Prescription drug benefits

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

A. <u>A new drug classification system would improve prescription drug coverage and access</u>

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

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

[126] See also, e.g., *Schmitt v. Kaiser Found. Health Plan of Wash*., 965 F.3d 945, 949 (9th Cir. 2020) (affirming that § 1557 prohibits discriminatory benefit designs); *Doe v. CVS Pharmacy, Inc.,* 982 F.3d 1204, 1211–12 (9th Cir. 2020) (affirming that a beneficiary must have "meaningful access" to a benefit).
[127] Héctor Hernández-Delgado & Wayne Turner, *supra* note 58, at 7-10.

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

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

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

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

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

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

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

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

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

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

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

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[132] 88 Fed. Reg. 82599.
[133] 88 Fed. Reg. 82600.
[134] *See*, *e.g.*, Alison Sexton Ward, et al., *Benefits of Medicare Coverage for Weight Loss Drugs,* Schaeffer Center for Health Policy & Economics, University of Southern California (April 18, 2023), https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/.
[135] 88 Fed. Reg. 82601.

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

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

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

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

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

[139] *Id.* at 7–8.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[145] 42 U.S.C. § 300ff–12.
[146] Ctrs. for Medicare & Medicaid Servs., *Medicaid Program; Ensuring Access to Medicaid Services Proposed Rule*, 88 Fed. Reg. 27960 – 28089 (May 3, 2023), https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08959.pdf.
[147] *Id.* at 28,078–79.
[148] 78 Fed. Reg. 12845.

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

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

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

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[149] *See* Patient Protection and Affordable Care Act, 80 Fed. Reg. 10749, 10817 (Feb. 27, 2015), https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.
[150] 87 Fed. Reg. 74100. We recognize that HHS may have contributed to the confusion when it suggested in the NBPP 2020 proposed rule that "when a plan covers a brand drug where a generic exists, the brand drug would no longer be considered EHB." 84 Fed. Reg. 289-290. However, no issuer or PBM can reasonably rely on dicta in the preamble of a proposed rule as a statement of law or administration policy.
[151] Héctor Hernández-Delgado & Wayne Turner, *supra* note 58, at 61–62 (citing *2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, Express Scripts, https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits); Meghan Pasicznyk, *Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, Evernorth (Oct. 7, 2021), https://www.evernorth.com/articles/reduce-costs-for-health-care-plans-with-copay-program-assistance.
[152] *See*, *e.g.*, Sally Greenberg, *Congress must fix loophole that is costing patients at the pharmacy*, The Hill (July 26, 2021), https://thehill.com/opinion/healthcare/564821-congress-must-fix-loophole-that-is-costing-patients-at-the-pharmacy/; Aimed Alliance, *Non-Essential Health Benefits and Copay Maximers*, Aimed Alliance, https://aimedalliance.org/non-essential-health-benefits-and-copay-maximizers/.
[153] 42 U.S.C. § 18022(b)(5).

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

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

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

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

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[154] *Johnson & Johnson Health Care Sys. v. Save On SP*, LLC, CA No. 22-2632, Complaint ¶10 (May 4, 2022), https://www.drugchannelsinstitute.com/files/22-cv-02632.pdf.
[155] *Id.* Opinion and Order (Jan. 1, 2023), https://aimedalliance.org/wp-content/uploads/2023/07/SaveOnSP-Decision-Denying-Motion-to-Dismiss.pdf. To date, the U.S. Department of Justice has not filed a statement of interest in the case.
[156] Johnson & Johnson, *Comments to Pennsylvania Department of Insurance Commonwealth Essential Health Benefits Benchmark Plan* (Sept. 1, 2023), https://www.insurance.pa.gov/Coverage/health-insurance/EHB-BenchmarkPlan/Documents/PublicComment_23/34_JJ_PA%20EHB%20Benchmark%20Comment_09012023.pdf.
[157] *See 2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, Express Scripts, *supra* note 151.

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

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

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

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

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[158] Iona University, *SaveOnSP – Variable Copayments for Certain Specialty Pharmacy Medications*, https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain.
[159] About Express Scripts, https://www.express-scripts.com/frontend/open-enrollment/networkhealthplan/about (last visited Dec. 14, 2023).
[160] Express Scripts, *A richer specialty benefit with room to plan and grow,* https://www.express-scripts.com/corporate/index.php/solutions/lowering-costs#saveonsp (last visited Dec. 14, 2023).
[161] Cigna, *Pay $0 For Select Specialty Medications*, https://hr.richmond.edu/benefits/insurance/medical-plans/pdf/SaveonSP.pdf.
[162] *See The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies*, Drug Channels (Mary 23, 2023), https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html.
[163] CVS Caremark, *The PrudentRx Copay Program Frequently Asked Questions*, https://www.caremark.com/portal/asset/TRS_PrudentRx_Member_FAQ.pdf (last visited Dec. 13, 2023). In a footnote, Caremark suggests that its definition of EHB is "authorized by the U.S. Department of Health and Human Services."

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

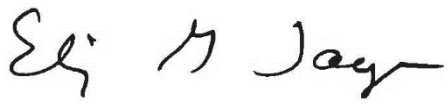
We strongly support the proposed § 156.122(f), which would codify the long-held policy that prescription drugs that exceed the minimum coverage requirements are EHB and subject to ACA cost sharing protections. We further call upon HHS to monitor compliance and end these unlawful and harmful schemes once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

Conclusion

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

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

Sincerely,



Elizabeth G. Taylor
Executive Director

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