August 15, 2022

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

Dear Director Montz:

Thank you for our productive meeting discussing Essential Health Benefits (EHB) in July. This letter is to follow up on some of the issues we touched upon, as well as our earlier letter to Secretary Becerra documenting deficiencies under the current EHB benchmarking process and how to use EHB to advance health equity.¹

While we maintain that the Department of Health and Human Services (HHS) should establish robust national standards in all ten EHB benefit categories, we believe CCIIO should more immediately propose improvements in two categories – prescription drugs and maternity care – as part of the upcoming Notice of Benefit and Payment Parameter (NBPP) for 2024 rule. These changes could significantly improve health care access for millions enrolled in health plans subject to EHB coverage standards. We believe that issuers can implement these improvements with minimal disruption to insurance markets, while advancing health equity.

Benefit changes to propose in the upcoming NBPP for 2024

As noted in our earlier letter, Congress gave the Secretary of HHS considerable authority to define EHB. The NBPP for 2024 provides an important opportunity to fulfill the promise of the ACA and improve benefits in two key areas.

Prescription drugs

The current prescription drug standard – the greater of one drug per U.S. Pharmacopeia (USP) class and category, or the number in a state’s benchmark plan – has proven inadequate to meet the needs of many patients.

We suggest the following changes (proposed additions in **bold and italics**):

§ 156.122 Prescription drug benefits.
(a) A health plan does not provide essential health benefits unless it:
   (1) Subject to the exception in paragraph (b) of this section, covers all of the following:
      (i) At least the greater of:
         (A) **One** drugs in every United States Pharmacopeia (USP) category and class; or
         (B) The same number of prescription drugs in each category and class as the EHB-benchmark plan;
      (ii) **All or substantially all drugs described in** 42 U.S.C. § 1395w–104(b)(3)(G)(iv); and
      (iii) **All medications approved by the FDA to treat opioid use disorder and opioid overdose reversal agents, which shall not be subject to limitations such as prior authorization, step therapy requirements, or concurrent counseling requirements.**

Under the current rules, 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

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3 45 C.F.R. § 156.122(a)(1).
tablet therapy for HIV. 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. 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.

Like HIV, treatment for persons with epilepsy is also 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. Covering only one drug in each class and category fails to account for these conditions.

For these reasons, 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. Protected classes were explicitly included in Part D “because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be

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6 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).


8 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.
substantially discouraged from enrolling in certain Part D plans.”

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.

Finally, requiring EHB plans to cover all three medications used to treat opioid use disorder (Buprenorphine, Methadone, and Naltrexone) and the overdose reversal agent Naloxone, would address the ongoing overdose crisis devastating so many communities across the country. These medications are effective in reducing the effects of substance use disorders, yet most people, particularly individuals in Marketplace plans, struggle to access them. 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. Similarly, the vast majority of state benchmark plans are either silent or explicitly exclude methadone for opioid use disorder treatment. While some states have used the benchmarking flexibilities to improve access to opioid use disorder treatment, CCIIO should close the remaining gaps in all other states through a federal coverage requirement.

We also believe making these changes to the prescription drug standard would have a small effect on premiums in the Marketplace. A cursory review of EHB benchmark plans shows that most already exceed the current federal minimum in most USP classes and categories. In fact, most states would only need to add one drug in less than 15 drug classes and categories out of more than 130 listed. For example, Tennessee’s current EHB benchmark plan would need to add only one drug in approximately 12 drug classes and categories under the standard we propose for § 156.122(a)(1)(i); Texas would only need to add one drug in 13 drug classes and categories; and Florida would need to add one drug in only 9 drug category and classes. Moreover, benchmarking changes to add coverage of opioid use disorder medications in Illinois and Oregon demonstrate the small actuarial impact such a requirement would have. These states incorporated mandatory opioid use disorder treatment coverage into

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9 Medicare Prescription Drug Benefit Manual Chapter 6, § 30.2.5.
their EHB benchmarks without running afoul of actuarial limitations, precisely because their actuarial analyses showed that it would not increase premiums significantly.\textsuperscript{14}

Furthermore, because of the impact it would have on various communities across the country, we believe proposals like this to address the opioid overdose epidemic may be supported by different stakeholders and policymakers across the political spectrum, minimizing its opposition and the impact of potential litigation challenging it. Finally, we note that improving the EHB prescription drug coverage standard is less likely to cause disruption or be met with court challenge, because HHS would be improving an already established national coverage standard.

\textbf{Maternity Care}

There is no current EHB definition or minimum standard for maternity care. There should be. Deficiencies in this EHB category have a tremendous impact on women and other people who may become pregnant, as well as future generations.\textsuperscript{15} Moreover, the high rates of maternal health mortality in the U.S. support CCIIO taking bold action to improve maternity care. This is particularly true for Black women, who are three times more likely to die from pregnancy-related complications than White woman, and for American Indian and Alaskan Native women, who are twice as likely to die from pregnancy-related complications that White women because of disparities due to racism and implicit bias.\textsuperscript{16} Pregnant people still struggle to access

\begin{itemize}
\item \textsuperscript{14} See, e.g., Wakely Consulting Group, State of New Mexico: Office of the Superintendent of Insurance: Benchmark Plan Benefit Valuation Report (March 9, 2020), at 7, \url{https://www.osi.state.nm.us/wp-content/uploads/2020/03/2022-Essential-Health-Benefits-EHB-Actuarial-Report.pdf}, finding 0.00% impact on Per Member Per Month costs by requiring plans to cover all four opioid reversal drugs.
\item \textsuperscript{15} 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. See Nora Ellmann & Jamille Fields Allsbrook, Ctr. for American Progress, \textit{States’ Essential Health Benefits Coverage Could Advance Maternal Health Equity} (Apr. 30, 2021), \url{https://www.americanprogress.org/issues/women/news/2021/04/30/498751/states-essential-health-benefits-coverage-advance-maternal-health-equity/}.
\end{itemize}
adequate care and Black, Indigenous, and other people of color are more likely to be underinsured and to have difficulty affording health care.\textsuperscript{17} We therefore urge CCIIO propose a national minimum coverage standard for maternity care in the upcoming NBPP that adopts national clinical guidelines, including oral health services.

We propose the following addition to the EHB federal rules:

\section*{§ 156.115 Provision of EHB.}

(a) Provision of EHB means that a health plan provides benefits that –

\begin{itemize}
  \item \textbf{(7)} With respect to maternity care include:
    \begin{itemize}
      \item \textbf{(i)} Care consistent with the joint Guidelines for Perinatal Care from the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, including oral health services;
      \item \textbf{(ii)} Midwife services, and;
      \item \textbf{(iii)} Full spectrum doula care.
    \end{itemize}
\end{itemize}

Prenatal care varies across health insurance coverage, individuals, and health needs. Most pregnant people receiving prenatal care will follow a schedule set by who is providing the care. According to American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) joint Guidelines for Perinatal Care (hereinafter “Joint Guidelines”), in general a pregnancy without complications is examined every four weeks for the first twenty-eight weeks of gestation, then every two weeks until thirty-six weeks of gestation, finally every week until birth.\textsuperscript{18} Individuals with pregnancies with complications and people with obstetric or medical concerns will require more frequent care for their pregnancies.

The Guidelines on Perinatal Care provide a comprehensive continuum of care that should serve as the basis for the maternity care benefit. By establishing the Guidelines as the national standard, CCIIO can help address the wide variation in maternity care and help fill coverage gaps by requiring a baseline standard of care.

\textsuperscript{17} See, Ctr. for American Progress, Health Disparities by Race (May 2020), \url{https://www.americanprogress.org/article/health-disparities-race-ethnicity/}.

\textsuperscript{18} Am. College of Ob. & Gyn., and Am. Academy of Ped., \textit{Guidelines for Perinatal Care Eighth Edition} (September 2017), \url{https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx}. 
Dental Care

CCIIO should expressly include oral health services within the definition of the maternity care benefit, as part of a requirement to provide maternity care consistent with the Joint Guidelines,, which list dental care as an area of concern and discuss a list of oral health concerns that are common during pregnancy.\(^\text{19}\) Despite the importance of oral health during pregnancy and despite the growing concern for maternal health and mortality in the United States, pregnant people on Marketplace coverage do not have access to dental care as an EHB. When pregnant people do not have access to dental care, they may be vulnerable to oral health conditions that are harmful to their health and the future health of their baby, as pregnancy itself can increase risks for oral health conditions.\(^\text{20}\)

The ADA 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;\(^\text{21}\) and a condition called Pyogenic granuloma or oral pregnancy tumor.\(^\text{22}\) In addition, according to the Centers for Disease Control and Prevention (CDC), approximately sixty to seventy five percent of pregnant women have gingivitis, which is an early state of periodontal disease that can be worsened due to changing hormones during pregnancy.\(^\text{23}\) ACOG estimates that approximately forty percent of pregnant women have some form of periodontal disease.\(^\text{24}\) Periodontal disease is an inflammatory disease that can result in the loss of connective tissue and support leading to tooth loss and has been linked to several health conditions such as

\(^{19}\) Id.


\(^{22}\) Shailesh M. Gondivkar, Amol Gadbail, & Revant Chole, Oral pregnancy tumor, CONTEMP CLIN DENT. (2010), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3220110/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3220110/).

\(^{23}\) Ctrs for Disease Control and Prevention. Pregnancy and Oral Health, [https://www.cdc.gov/oralhealth/publications/features/pregnancy-and-oral-health.html](https://www.cdc.gov/oralhealth/publications/features/pregnancy-and-oral-health.html) (last visited May 14, 2022). This report 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.

Likewise, poor oral health during pregnancy can lead to negative pregnancy outcomes such as preterm birth, low birth weight, and preeclampsia. While the connection between periodontal disease and poor pregnancy outcomes requires more research, a link between the two is likely. 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. The CDC considers preterm birth and low-birth weight to be in the top five leading causes of infant death in the United States in 2018. While hypertensive disorders like preeclampsia have declined as a factor in maternal mortality, they still remain responsible for approximately six percent of maternal deaths. To protect mothers and infants it is imperative that every step to reduce maternal and infant mortality is taken.

Further, 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. In addition, high levels of cariogenic bacteria in mothers can lead to increased cavities.

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27 CDC, *supra* note 23.
in their infants.\textsuperscript{31} This relationship has also been observed with a mothers’ tooth loss and their child’s cavities. The children of mothers with high levels of tooth loss were more than three times as likely to have more cavities compared to children whose mothers had no or moderate tooth loss. 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.\textsuperscript{32} Children with oral health concerns are almost three times more likely to miss school because of dental pain.\textsuperscript{33}

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.\textsuperscript{34} 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.\textsuperscript{35}

Pregnant people are also less likely to receive dental care. Approximately forty six percent of pregnant women in the U.S. report having dental cleaning during their pregnancy and this number varies depending on socioeconomic factors. Thirty-six percent of pregnant women report that it has been more than a year since their routine dental visit, and twenty-eight percent note that they have not received routine dental care in at least two years.\textsuperscript{36} 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.\textsuperscript{37}

\begin{itemize}
\item \textsuperscript{32} 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), \url{https://jada.ada.org/article/S0002-8177(14)61498-7/fulltext}.
\item \textsuperscript{33} CDC, \textit{supra} note 16.
\item \textsuperscript{34} D.M. Shearer et al., Maternal oral health predicts their children’s caries experience in adulthood, 90 J DENT RES. 672-677 (2011), \url{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3144114/}.
\item \textsuperscript{35} 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), \url{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5972135/}.
\item \textsuperscript{36} Id.
\item \textsuperscript{37} Id.
\end{itemize}
Other studies have also shown that dental care is expensive and inaccessible for many people. The Health Policy Institute (HPI) for the ADA found that while dental insurance coverage was expanding (uninsured working-age adults reduced from thirty-four percent to twenty-seven percent), cost is still an important barrier for accessing dental care. 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.”

Because oral health services are generally excluded from EHB coverage for adults, many people cannot access such services, even as part of maternity care. 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 the dentist within the past year, fifty-nine percent noted cost as the reason. 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.

Finally, we believe CCIIO can add oral health services to the maternity care benefit category, without the need to change the regulations at 45 C.F.R. § 156.115(d), which says: “An issuer of a plan offering EHB may not include routine non-pediatric dental services…” The Secretary has authority to determine that oral health services delivered as part of the maternity care benefit category are not “routine” within the meaning of 45 C.F.R. § 156.115(d). Pursuant to the Supreme Court’s decision in Auer v Robinson, when a previous regulation is ambiguous, courts should defer to the agency’s interpretation of the regulation unless the interpretation is “plainly erroneous or inconsistent with the regulation,” or there is other “reason to suspect that the interpretation does not reflect the agency’s fair and considered judgment on the matter in

39 Id.
41 Id.
question." Given the considerable evidence supporting the need to provide oral health services to pregnant and postpartum individuals, interpreting "routine" under 45 C.F.R. § 156.115(d) as not including oral health services in the context of maternity care, will likely fall under permissive agency interpretations under Auer deference.

**Midwifery & doula care**

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. The COVID-19 public health emergency has also propelled an increased interest in home births. 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 to 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, or miscarriage. Doula care is among the most promising approaches to combating disparities in maternal health and improving the experience of birth. 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 sections. Doulas can also help reduce the impacts of racism and racial bias in health care on pregnant women of color by providing

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individually tailored, culturally appropriate, and patient centered care and advocacy. During the postpartum period, doulas can help with the transition from pregnancy to parenthood including lactation support, emotional support, and soothing techniques.

At a minimum, we recommend that plans should cover three prenatal doula visits and three postpartum doula visits in addition to covering labor and delivery separately. 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. Doula care should be covered without a supervision requirement and instead by recommendation of a physician or licensed practitioner of the healing arts.

In sum, CCIIO can, through the upcoming NBPP for 2024 (or other rulemaking), significantly expand the EHB maternity care benefit. Expanding and improving maternity care will reap substantial rewards in the form of better health outcomes for both pregnant and perinatal individuals and babies. Given the ignominy of Dobbs and the reality of forced birth, improvements to maternity care are needed more now than ever.

**Conclusion**

We appreciate your continuous engagement on these matters and your willingness to work with us to improve coverage of EHBs in the Marketplace. Improving coverage of maternity care services and prescription drugs is an achievable goal that properly balances the need to close gaps in coverage with the costs associated with doing so. Moreover, these actions would be in line with several executive orders signed by President Biden to strengthen Marketplace coverage, secure access to reproductive health care services, and advance racial equity in health care.  

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As always, we remain available for further discussion and to answer any questions about the content of our letters. If you have any questions, please feel free to contact Héctor Hernández-Delgado at hernandez-delgado@healthlaw.org; or Wayne Turner at turner@healthlaw.org.

Sincerely,

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