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January 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information; Essential Health Benefits. Centers for Medicare & Medicaid Services, Department of Health and Human Services (CMS-9898-NC)

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Request for Information (RFI) on Essential Health Benefits (EHB) published in the *Federal Register* on December 2, 2022. We are pleased that CMS has begun the process through this RFI, as required by the Affordable Care Act (ACA), to periodically review and update the EHB framework to address gaps in coverage or changes in evidence base. Enactment of the ACA and implementation of the EHB have resulted in reducing the number of uninsured individuals and expanded coverage of critical benefits, such as maternal health benefits and mental health and substance use benefits. Yet, there have been numerous changes in the health care delivery, e.g., telehealth use, and in health needs and care over the last decade, including the COVID-19 public health emergency and other infectious disease epidemics, the substance use disorder and overdose epidemics, the mental health crisis, health equity concerns, and the maternal mortality crisis, but the EHB framework has not been updated. The AMA believes that the time is ripe for CMS to reconsider EHB and whether and how changes might be necessary, and we offer some initial thoughts and recommendations below in response to some of the specific questions in CMS' RFI.

Barriers to Accessing Services Due to Coverage or Cost

The application of prior authorization, step therapy, or other utilization management requirements to EHBs creates a barrier to care that is antithetical to the ACA's goal of ensuring that all patients in qualified health plans (QHPs) have access to the EHB package. An EHB package than cannot be accessed due to utilization management requirements realistically has no value and is not a "benefit."

Utilization management tactics are overused, costly, opaque, burdensome to physicians, and harmful to patients due to delays in care. The AMA has long been concerned about the prior authorization process and its negative impact on patients, as we frequently hear from physicians and patients about delays in care that result from these insurer protocols. In fact, AMA survey data show that 93 percent of physicians report care delays because of prior authorizations. AMA survey data also show that 34 percent of physicians report that prior authorization has led to a serious adverse event for a patient in their care, such

as hospitalization, permanent impairment, or death. Not surprisingly, the same survey found that 91 percent of physicians see prior authorization as having a negative effect on their patients' clinical outcomes and 82 percent of the physicians surveyed indicated that patients abandon treatment due to authorization struggles with health insurers.

Additionally, application of prior authorizations to EHBs is not an appropriate or effective cost savings method, as these requirements are penny wise and pound foolish. For example, applying prior authorization to HIV Pre-Exposure Prophylaxis (PrEP), an extremely effective method of HIV prevention, may result in fewer prescriptions, reduced access, and treatment-abandonment by patients. While this may result in an immediate cost-savings for the health plan, the annual costs of treatment for HIV are significantly higher than the annual costs of PrEP. More importantly, the societal costs of establishing barriers to such preventive treatments are immeasurable.

Prior authorization requirements are also reducing access to EHBs by reducing access to the physicians who provide them. Physician offices find themselves using inordinate amounts of time and resources submitting prior authorization paperwork to justify medically necessary care for their patients to health plans. AMA survey data show that, on average, physician practices complete 41 prior authorizations per physician per week and that 40 percent of physicians report that there are staff members in their offices that exclusively work on prior authorizations. This adds up to nearly two business days, or 13 hours, each week—dedicated to completing prior authorizations rather than providing patient care. It is also important to recognize that these prior authorization burdens continue to place administrative pressure on physician practices as they face staff shortages and attempt to regain their footing following the COVID-19 pandemic.

Even insurers have recognized that prior authorization is overutilized and is ripe for reform. In 2018, in what looked like progress, health plans recognized the need to reduce the burden of prior authorization and agreed to make a series of improvements to the prior authorization process. Despite increasing evidence of harm, most health plans have made no meaningful progress on reforms as evidenced by additional survey data from the AMA. Therefore, it is critical that CMS ensure that prior authorization and other utilization management tools do not stand in the way of patients' access to EHBs.

The AMA strongly supports strengthening mental health and substance use disorder (SUD) services as EHBs and doing more to ensure health insurers actually provide them. Few people who need treatment for mental illness or an SUD are able to access it.[1] A key reason why mental health and SUD benefits go unrealized for thousands of Americans is health insurers' widespread, repeated failures to comply with state and federal laws, including the 2008 Mental Health Parity Addiction and Equity Act (MHPAEA). Congress has received ample evidence of these failures,[2] which also are found by state

[1] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[2] See, for example, the January 25, 2022 U.S. Departments of Labor, Health and Human Services, Treasury "2022 Mental Health Parity and Addiction Equity Act Report to Congress." Available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.

departments of insurance with increasing frequency.[3] Insurers' violations include failure to conduct comparative analyses, failure to provide the generally accepted standard of care for MH/SUD services and implementing greater barriers for MH/SUD services than for medical and surgical benefits. As long as payers are allowed to wantonly violate the law, however, the promised benefits of mental health or SUD care as EHBs will be benefits in name only. Almost 107,000 Americans died last year from a drug-related overdose, according to the National Center for Health Statistics,[4] with increases among all ages and races. **The AMA strongly urges, therefore, increased enforcement of state and federal parity laws so patients can receive the benefits they pay for—and that the law requires**.

Prior authorization is a particularly pernicious type of structural barrier that hits exceptionally hard for individuals with a mental illness or SUD. Prior authorization of buprenorphine is common in Marketplace plans.[5] Consider that when an individual with a mental illness or substance use disorder is unable to get the care recommended by his or her physician because of prior authorization or some other unnecessary administrative requirement, the result may range from delayed ability to take a life-saving medication to being denied access to life-saving residential or in-patient care.[6] If an individual with an SUD is turned away at the pharmacy counter because of a health insurer's or pharmacy benefit manager's (PBM) prior authorization requirements for buprenorphine, for example, it would not be surprising for that patient to return to illicit drug use and increased risk for overdose. Prior authorization and other barriers to medication for opioid use disorder also disproportionately affect people who are Black.[7] Removing prior authorization for medication for opioid use disorder saves lives.[8] **To reduce inequities, improve care and save lives, the AMA urges a ban on prior authorization and other harmful utilization management for all forms of medications to treat opioid use disorder.** There is no reason—in the midst of an increasingly deadly epidemic—that any health insurer or PBM should be allowed to continue this practice.

The AMA also urges action to help reduce fetal and maternal mortality for individuals with an SUD. At a threshold level, every pregnant person with an SUD deserves the same care and compassion as anyone else with an SUD. The AMA agrees with the Office of National Drug Control Policy (ONDCP) that "Medications for OUD reduce risk of relapse and death for pregnant and postpartum women and improve pregnancy outcomes."[9] The AMA supports assurances/conditions that pregnant, postpartum, and

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[3] Select examples can be found at "State Parity Regulatory Enforcement Actions." The Kennedy Forum. Accessed January 24, 2023, https://www.paritytrack.org/resources/state-parity-enforcement-actions/.

[4] National Center for Health Statistics. Drug Overdose Deaths in the United States, 2001-2021. NCHS data Brief No. 457, December 2022. Available at https://www.cdc.gov/nchs/products/databriefs/db457.htm.

[5] Nguyen TD, Chua K, Andraka-Christou B, Bradford WD, Simon K. Trends in Buprenorphine Coverage and Prior Authorization Requirements in US Commercial Formularies, 2017-2021. *JAMA Health Forum.* 2022;3(7):e221821. doi:10.1001/jamahealthforum.2022.1821.

[6] "Study: Lifting addiction meds rule would save N.Y. lives, costs." Albany Times Union. December 10, 2019. Available at https://www.timesunion.com/news/article/Study-Lifting-rule-on-addiction-meds-would-save-14886954.php.

[7] Mark, Tami L. PhD, MBA; Goode, La Sonya A. MPH; McMurtrie, Gary BA; Weinstein, Lara MD, MPH, DrPH; Perry, Rebecca J. MSc. Improving Research on Racial Disparities in Access to Medications to Treat Opioid Use Disorders. Journal of Addiction Medicine ():10.1097/ADM.0000000000001104, October 26, 2022. | DOI: 10.1097/ADM.0000000000001104.

[8] Mark TL, Parish WJ, Zarkin GA. Association of Formulary Prior Authorization Policies With Buprenorphine-Naloxone Prescriptions and Hospital and Emergency Department Use Among Medicare Beneficiaries. *JAMA Netw Open.* 2020;3(4):e203132. doi:10.1001/jamanetworkopen.2020.3132.

[9] "Substance Use Disorder in Pregnancy: Improving Outcomes for Families." The White House Executive Office of the President. Office of National Drug Control Policy. October 21, 2022. Available at

parenting individuals receive medications for opioid use disorder and other medications when recommended by the individual's physician. **To the extent that entities receive federal money, they should be required to attest that either they provide medications for opioid use disorder or if they do not, and that the entities do not discriminate or exclude individuals receiving medications for opioid use disorder from receiving any services or benefits.**

Utilization of Telehealth

The success of telehealth technology adoption during the public health emergency (PHE) has made it abundantly clear that outdated and arbitrary restrictions on accessing telehealth services make no sense with the technological advances we have seen to this point. Telehealth technologies allow physicians to increase continuity of care, extend access beyond normal clinic hours, and help mitigate the effects of physician shortages, especially for rural and other underserved populations. By allowing telehealth services to be integrated with in-person services and remote monitoring, the flexibilities that became available during the PHE have helped health systems and physician practices focus more on chronic disease management, enhance patient wellness, improve efficiency, provide higher quality of care, and increase patient satisfaction. These hybrid models of virtual and in-person care have resulted in a recognition from patients, physicians, and other health professionals that telehealth offers an effective and convenient way to provide health care services in many circumstances. Behavioral health services are a specifically significant case where telehealth has proven to be an exceptional value added on to the augmented health care experience that patients have had to adopt because of the COVID-19 pandemic.

Lack of access to appropriate medical care is one of the many indicators of health inequity that was made abundantly clear during the pandemic. Specifically, to address concerns about the barriers to mental health and substance use disorder treatment, the government relaxed requirements related to telehealth mental health services for Medicare beneficiaries.[10] Due to the previous outdated and limiting circumstances surrounding telehealth regulations, i.e., the "originating site" requirement, Medicare coverage of telehealth services was very limited. With the flexibilities granted by the PHE, beneficiaries from all over the country were now allowed to receive these services in their home rather than needing to travel to receive appropriate medical care.

We applaud the steps the Administration and Congress have taken to extend access to the flexibilities that the PHE originally granted around telehealth services, through the end of 2024. Behavioral health services have sensitivities attached to these conditions that are positively addressed by the comfort, convenience, and privacy that a telehealth visit can afford the patient. Moreover, patients being treated for health conditions that possibly have social stigma attached may find this modality best meets their needs at the point of care when they are the most vulnerable. Not only did continued telehealth access during the PHE help control infectious illness spread, but it also allowed for uninterrupted care ultimately resulting in better, more consistent treatment on both the patient and the provider side.

The AMA continues to study the changing landscape as it relates to coverage, payment, and access to telehealth, and data suggest that telehealth has and will continue to play an important role in increasing access to care. We encourage health plans to establish policies for telehealth as a modality for delivering

https://www.whitehouse.gov/wp-content/uploads/2021/10/ONDCP_Report-Substance-Use-Disorder-and-Pregnancy.pdf.

[10] "*FAQs on Mental Health and Substance Use Disorder Coverage in Medicare*," https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/, (Jan 2023).

care and not a service separate and distinct from care provided via other modalities such as in-person. AMA policy supports improvements to the EHB benchmark plan selection process to ensure limits and exclusions do not impede access to health care and coverage.

Addressing Social Determinants of Health and Maternal Mortality Rates

The AMA recognizes racial and ethnic health disparities as a major public health problem in the U.S. and as a barrier to effective medical diagnosis and treatment. A commitment to health equity means we must address the social determinants of health (SDOH), and we must elevate and name the root causes of why health inequities exist and how they came to be both in society and at the institutional level. Healthy People 2030 defines SDOH as "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."[11] As the Centers for Disease Control and Prevention (CDC) explains, differences in SDOH contribute to the stark and persistent chronic disease disparities in the U.S. among racial, ethnic, and socioeconomic groups, systematically limiting opportunities for members of some groups to be healthy.[12]

CMS should consider using reliable sources of regularly updated evidence on health-related social needs, such as the Commonwealth Fund, PCORI, and AcademyHealth. A 2022 Commonwealth Fund review including return on investment reported strong or moderate evidence for providing access to affordable housing with supportive social services to elderly people, home delivered meals with or without medical tailoring, socialization, and safety checks, participation in the Supplemental Nutrition and Assistance Program (SNAP), rideshare transportation for low-income primary care patients, home visits with nursing and occupational therapy plus home modifications and assistive equipment for impaired physical function, multi-disciplinary or social worker enhanced care coordination or care management patients with conditions putting them at high risk of health care use, and community health worker support for patients after hospital discharge or having a recent emergency room visit or in primary care with a chronic disease in poor control or with asthma triggered by the home environment. PCORI offers additional evidence around legal assistance and other interventions.

Ending systemic racism and biases perpetuated in maternity care must be a holistic approach. The reasons for the overall increase in maternal mortality rate (MMR) and severe maternal morbidity (SMM) are complex and multifactorial. According to the CDC, for every pregnancy-related death, an average of three to four contributing factors were identified, at multiple levels, including community, health facility, patient/family, provider, and system. Studies adjusting for sociodemographic and reproductive factors have not explained the racial gap in pregnancy-related mortality in most studies. For example, Black women have been found to be at an elevated risk regardless of income, education, or geographical location. The health care community is increasingly recognizing the significant role that structural racism and implicit bias in American society, including in the health care system, play in contributing to stark health inequities. To address systemic racism and biases in maternity care a number of issues will have to be tackled including enhancing data tracking and analysis of maternal and pregnancy-related morbidity and mortality events in order to stop preventable complications; integrating structural competency, increasing cultural sensitivity and implicit bias training opportunities; expanding access to affordable

[11] Office of Disease Prevention and Health Promotion, US Department of Health and Human Services. Social Determinants of Health. Healthy People 2030. Social Determinants of Health. Available at: https://health.gov/healthypeople/objectives-anddata/social-determinants-health.

[12] Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Social Determinants of Health. Available at: https://www.cdc.gov/chronicdisease/programs-impact/sdoh.htm.

health insurance; and working with partners from different sectors and with patients to better inform system changes and improvements. Additionally, narratives from the lived experiences of Black women indicate there is a rupture of trust between Black women and the health care system that must also be addressed. **In order to adequately address this multifactorial problem a minimum maternity and newborn care essential benefit standard should be set so that women across the country can be guaranteed the same minimum standard of care.** This should include holistic care including not requiring a referral or precertification for obstetrical and gynecological care, coverage of ultrasounds, and allowing pregnancy coverage for all pregnant individuals even if they are claimed as dependents.

Health insurance is critical to obtaining access to maternal health care. Moreover, a lack of insurance can lead to negative health outcomes and increase inequities in maternal care. Uninsurance challenges during and after pregnancy are due, in part, to the patchwork nature of publicly supported coverage options potentially available for pregnant and postpartum women that vary by state of residence, income, and immigration status.[13] For women with higher incomes, a steep "subsidy cliff" makes premium payments for Marketplace plans far more expensive as soon as income exceeds 400 percent of the federal poverty level, potentially preventing women from obtaining affordable insurance.[14] This can be especially challenging when women unexpectedly lose access to employer-sponsored insurance, as has frequently been the case during the COVID-19 pandemic.[15] **Becoming pregnant should be considered a qualifying life event, as part of the EHBs of any plan, and should enable a pregnant person to enroll in or change their health plan in the same way that the birth of a child is a qualifying event.** It is essential for the health of the mother and child that the mother receives adequate care during her pregnancy and not just postpartum.

Women are at elevated physical and behavioral health risk for 12 months following childbirth, so access to health care, and insurance coverage for that care, is essential. In general, one in three women in the U.S. experiences discontinuous insurance coverage ("churn") before, during, or after pregnancy.[16] Reducing this churn in the postpartum period can help to decrease disparities in maternal health outcomes.[17] Additionally, more than half of pregnancy-related deaths occur after the birth of the infant.[18] Specifically, and critical to policy decisions regarding postpartum care, support, and insurance coverage, approximately 16 percent of pregnancy-related deaths occurred between 1-6 days postpartum, 19 percent

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[13] Johnston et. al. Closing Postpartum Coverage Gaps and Improving Continuity and Affordability of Care through a Postpartum Medicaid/CHIP Extension. Urban Institute. January 2021. Available at: https://www.urban.org/sites/default/files/publication/103560/closing-postpartum-coverage-gaps-and-care-through-postpartummedicaid-chip-extension_2.pdf.

[14] Daniel McDermott. Impact of Key Provisions of the American Rescue Plan Act of 2021 COVID-19 Relief on Marketplace Premiums. KFF. March 15, 2021. Available at: https://www.kff.org/health-reform/issue-brief/impact-of-key-provisions-of-thehouse-covid-19-relief-proposal-on-marketplace-premiums/.

[15] Paul Fronstin and Stephen A. Woodbury. Update: How Many Americans Have Lost Jobs with Employer Health Coverage During the Pandemic? The Commonwealth Fund. January 11, 2021. Available at: https://www.commonwealthfund.org/blog/2021/update-how-many-americans-have-lost-jobs-employer-health-coverageduring-pandemic.

[16] Emily Eckert. Preserving the Momentum to Extend Postpartum Medicaid Coverage. Womens Health Issues. 2020 November December; 30(6): 401–404. Published online 2020 Sep 9. doi: 10.1016/j.whi.2020.07.006. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7480528/.

[17] *Id*.

[18] American College of Obstetricians and Gynecologists. Optimizing Postpartum Care. ACOG Committee Opinion Number 736. May 2018. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizingpostpartum-care.

occurred between 7-42 days postpartum, and 24 percent occurred between 43-365 days postpartum.[19] **Accordingly, postpartum women should be guaranteed access to the same health insurance for 12 months postpartum as part of the EHB provided by health insurance plans to reduce churn and increase health outcomes for the mother and child. This guarantee would align with the expansion efforts that are currently being undertaken by Medicaid and CHIP.**

The American College of Obstetricians and Gynecologists (ACOG) recommends that postpartum care be an ongoing process, rather than a single visit, with services and support tailored to each woman's needs.[20] Nevertheless, approximately 40 percent of women do not attend a postpartum visit.[21] Critical barriers to obtaining postpartum care include lack of child care, inability to obtain an appointment, mistrust of health care providers, and limited understanding of the value of the visit.[22] These barriers are even more challenging for patients with limited resources, decreasing attendance rates and contributing to disparities.[23] Notably, 23 percent of employed women return to work within 10 days of giving birth, and an additional 22 percent return to work between days 10 and 42 postpartum. Only 14 percent of American workers—and only five percent of low-wage workers—have access to paid leave.[24] The AMA agrees with ACOG in recommending that obstetric care physicians ensure that women, their families, and their employers understand the need for continued recovery and support for postpartum women.[25] Recognizing the burden of traveling to and attending an office visit, especially with the new responsibility of an infant, ACOG explains that in-person care may not always be required.[26] Telephone support during the postpartum period can reduce depression, improve breastfeeding outcomes, and increase patient satisfaction.[27] **Therefore, telehealth visits for postpartum care should be covered under EHB.** This coverage will help to increase attendance at postpartum checkups, reduce barriers surrounding childcare and work requirements, and lead to better overall health outcomes.

Additionally, **EHB should cover health education services including childbirth, parenting, breastfeeding, CPR, and newborn education services.** Certain states such as Vermont, Alaska, Maryland, and Massachusetts, already cover this under their benchmark plans. However, this should be covered by all state plans. Moreover, similar to Connecticut, comprehensive lactation visits should be provided for a few months postpartum. In this same vein, EHB should cover multiple types of breast pumps including manual, electric, and battery-operated. Many states already cover breast pumps in some capacity, but many states limit coverage to only a certain type of pump. Moreover, both breastfeeding

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[19] Davis NL, et. al. Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008-2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2019. Available at: https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf.

[20] American College of Obstetricians and Gynecologists. ACOG Postpartum Toolkit. Available at: https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/publications/2018-postpartum-toolkit.pdf.

[21] *Id.*

[22] *Id.*

[23] American College of Obstetricians and Gynecologists. Optimizing Postpartum Care. ACOG Committee Opinion Number 736. May 2018. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizingpostpartum-care.

[24] American College of Obstetricians and Gynecologists. ACOG Postpartum Toolkit. Available at: https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/publications/2018-postpartum-toolkit.pdf.

[25] American College of Obstetricians and Gynecologists. Optimizing Postpartum Care. ACOG Committee Opinion Number 736. May 2018. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizingpostpartum-care.

[26] *Id.*

[27] *Id.*

support and breast pumps should be covered. Mothers should not have to choose between one or the other, especially considering that some mothers may ultimately be unable to breastfeed and may need to switch feeding methods to best accommodate their bodies and their children's needs.

As EHB change to ensure the best care possible for pregnant, birthing, and postpartum individuals it is important that these benefits cover holistic services and create a universal minimum standard so that individuals across the country can be assured quality care.

Advancing Equity through Communication and Access to Appropriate Language Services

Effective communication can have a profound impact on how patients and families perceive their care.[28] Research demonstrates that patient engagement in health care leads to measurable improvements in safety and quality.[29] Open communication between the medical team and patients and families can broaden perspectives and reduce patient avoidance of physicians/facilities and/or medical care in general.[30] Language services are an essential part of providing holistic health care in a patient-centered, language, and culturally appropriate way. "Language access services are designed to promote effective communication between [limited English proficiency] (LEP) persons and non-LEP persons. LEP persons do not speak English as their primary language and have a limited ability to read, write, speak, [sign,] or understand English. Language access services can include oral interpretation and written translation."[31]

Access to language services has been proven to improve communication, improve adherence to treatment regimen, improve diagnosis and treatment, and result in fewer complaints.[32] However, one of the top deterrents to providing language services is cost and the fact that "[l]imited reimbursement is available for language access services."[33] Due to the price associated with language services, physicians cannot be expected to provide and fund these translation services for their patients; when trained medical interpreters are needed, the costs of their services should be paid directly to the interpreters by health plans and physicians should not be required to participate in payment arrangements. **Therefore, health plans should cover language services and directly pay interpreters for such services to ensure that proper and effective care can be provided.**

Beyond ensuring that payment by health plans is provided for language services, it is important that plans inform individuals both verbally and in writing that language services are available and health plans should publish and validate standard patient assessment tools in multiple languages. This is especially important since there is evidence that beneficiaries have difficulty accessing language services that plans provide through call centers. "For example, one study found that only 69 percent of LEP persons calling plans could reach someone who spoke their primary language and were often unable to access translated documents from the plans."[34] **Since it is vitally important to provide access to language services to**

[28] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.
[29] Agency for Healthcare Research and Quality. Guide to Patient and Family Engagement in Hospital Quality and Safety. Content last reviewed December 2017. https://www.ahrq.gov/patient-safety/patientsfamilies/engagingfamilies/guide.html.
[30] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.
[31] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf.
[32] https://oig.hhs.gov/oei/reports/oei-05-10-00050.pdf.
[33] https://oig.hhs.gov/oei/reports/oei-05-10-00050.pdf.
[34] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf; http://www.nsclc.org.

ensure that high-quality health care is provided, health plans must start providing verbal and written language services as well as standard patient documents in multiple languages.[35] By requiring EHB to pay for proper interpreters and written materials in multiple languages EHBs would be aligning themselves with the direction that Medicare is headed in which is important for beneficiaries.

Underserved Populations in Rural Areas

"More than 46 million Americans, or 15 percent of the U.S. population, live in rural areas as defined by the U.S. Census Bureau….Rural Americans are more likely to die from heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke than their urban counterparts. Unintentional injury deaths are approximately 50 percent higher in rural areas than in urban areas, partly due to greater risk of death from motor vehicle crashes and opioid overdoses."[36] Additionally, rural populations tend to be older, poorer, have less access to health care, have riskier health behaviors, and have overall worse health outcomes than their urban counterparts. From 2007 to 2017, rural-urban mortality disparities increased for five of seven major causes of death tracked by Healthy People 2020: coronary heart disease, cancer, diabetes, chronic obstructive pulmonary disease, and suicide.[37]

Access to health care in rural jurisdictions impacts the ability of the public health system to focus on essential public health services and functions. Nearly 35 years ago, the Institute of Medicine's report on the "Future of Public Health" noted that the responsibility for providing medical care to individuals has drained vital resources and attention away from disease prevention and health promotion efforts that benefit the entire community.[38] Systemic bias in health care financing has been one of many factors leading to rural health disparities and should be eliminated through payment policy reform to help reduce the shortage of rural physicians.

Telehealth should be covered within EHB, especially for those in rural areas. Moreover, CMS should consider including transportation to and from medical appointments within EHB to ensure that patients can have proper access to health care. It is also critical that individuals in rural areas be covered for regular checkups for coronary heart disease, cancer, diabetes, chronic obstructive pulmonary disease, as well as screening for mental health and substance use disorders.

Gaps in Coverage: Chronic Diseases

Chronic diseases are major drivers of health care costs in the United States responsible for 90 percent of the nation's $4.1 trillion in annual expenditures.[39],[40] An estimated 30 percent of adults have more than

[35] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf.
[36] https://www.cdc.gov/ruralhealth/about.html.
[37] Yaemsiri S, Alfier JM, Moy E, et al. Healthy People 2020: Rural Areas Lag In Achieving Targets For Major Causes Of Death. Health Aff Proj Hope. 2019;38(12):2027-2031. doi:10.1377/hlthaff.2019.00915. See also AMA Board of Trustees Report 13-I-22, "Structural Urbanism and Impact on Rural Workforce Disparities."
[38] The Future of Public Health | The National Academies Press. Available at https://www.nap.edu/download/1091#.
[39] Buttorff C, Ruder T, Bauman M. Multiple Chronic Conditions in the United States [PDF -393kb] Santa Monica, CA: Rand Corp.; 2017.
[40] National Health Expenditure Data: Historical. Center for Medicare & Medicaid Services. December 15, 2021. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

one chronic condition.[41] The EHB include screening services for many of these chronic conditions, but enrollees need greater access to clinical services that prevent the health complications associated with chronic diseases such as hypertension, obesity, prediabetes, and type 2 diabetes. Many enrollees in these health plans are disproportionally affected by the negative health consequences of these conditions. While enrollment in ACA insurance plans has provided access to health insurance, the health plans vary by state, which can result in further inequities and additional burdens of cost sharing if someone is enrolled in a high deductible plan.

The AMA recommends parity between the clinical services and programs available in employer and other health plans to improve outcomes associated with hypertension, obesity, prediabetes, and type 2 diabetes. Improved access to self-measured blood pressure devices, lifestyle change programs and pharmacotherapies would help eliminate health disparities associated with access and other structural barriers to prevention and treatment. These treatment services and programs should be considered "essential" under the ACA's mandated 10 EHB categories. For example, self-measured blood pressure devices and lifestyle change programs should fall under the broad "preventive and wellness services and chronic disease management" category and fixed-dose combination hypertension drugs and anti-obesity medications should be covered under the "prescription drug" category.

Hypertension

CMS has called hypertension the most important modifiable risk factor for coronary heart disease, stroke, congestive heart failure, and end-stage renal disease. The Centers for Disease Control and Prevention (CDC) identifies heart disease as the leading cause of death in the United States.[42] The CDC also reports that unmanaged hypertension results in nearly 1,300 deaths every day.[43]

After a steady increase of US adults with controlled blood pressure, the numbers are now heading in the wrong direction, with an estimated 80 percent of those with hypertension not in control.[44] Monitoring BP at home using a SMBP home device is a key component in managing hypertension. When SMBP devices are used alongside other appropriate clinical interventions to manage hypertension, there is evidence to support improved medication adherence, reduction in BP and improved BP control.

The AMA recommends improving patient access to self-measured blood pressure (SMBP) devices and clinical services. For many people, BP measured outside of the office differs greatly from BP measured inside the office. SMBP monitoring is an evidence-based approach of measuring BP outside of the office. SMBP is a more accurate predictor of cardiovascular events and mortality than office-measured blood pressure. Current clinical guidelines and scientific statements recommend the use of out-of-office BP

[41] Boersma P, Black LI, Ward BW. Prevalence of Multiple Chronic Conditions Among US Adults, 2018. Prev Chronic Dis 2020;17:200130. DOI: http://dx.doi.org/10.5888/pcd17.200130.

[42] Centers for Disease Control and Prevention. (2021, December 21). Products - data briefs - number 427 - December 2021. Centers for Disease Control and Prevention. Retrieved September 26, 2022, from https://www.cdc.gov/nchs/products/databriefs/db427.htm.

[43] Centers for Disease Control and Prevention. Hypertension Among Adults in the United States: National Health and Nutrition Survey, 2017-2018. https://www.cdc.gov/nchs/data/databriefs/db364-h.pdf.

[44] Tsao, C. W., Aday, A. W., Almarzooq, Z. I., Alonso, A., Beaton, A. Z., Bittencourt, M. S., Boehme, A. K., Buxton, A. E., Carson, A. P., Commodore-Mensah, Y., Elkind, M. S. V., Evenson, K. R., Eze-Nliam, C., Ferguson, J. F., Generoso, G., Ho, J. E., Kalani, R., Khan, S. S., Kissela, B. M., … Martin, S. S. (2022). Heart disease and stroke statistics—2022 update: A report from the American Heart Association. Circulation, 145(8). https://doi.org/10.1161/cir.0000000000001052.

measurements for confirming a diagnosis of hypertension, titrating treatment, and following up to assess BP control.

Barriers to evidence-based treatments that may exist in some plans include:

- Limited coverage for certain medications: The specific medications that must be covered under the EHBs may vary by state, and some states may not cover fixed dose combination drugs that are shown to achieve hypertension control more quickly than single dose regimens.
- Limited coverage for certain treatments: The EHBs may not cover certain treatments or services that are commonly used to manage hypertension, such as telehealth visits or remote monitoring. This can make it difficult for individuals with hypertension to access care remotely or in non-traditional settings.
- The ACA does not specifically mention coverage for home blood pressure devices, which provide patients with the ability to monitor their blood pressure, identify any lifestyle changes that impact the reading while also consulting with their physician regarding any changes in medications. While some plans may cover these devices, there are variations from plan to plan and by state.
- The ACA does not cover SMBP education on devices, interpretation of results and follow-up monitoring by a physician-led health care team.
- Cost sharing: Even though EHB covers hypertension treatment, plans may have cost sharing such as deductibles, copays, or coinsurance. This can make it difficult for individuals with hypertension to afford the care they need, especially if they have a high-deductible plan.

Universal and consistent coverage and availability of SMBP devices and clinical services combined with access to fixed dose combination hypertension drugs, will improve control rates and contribute to a reduction in the medical conditions associated with uncontrolled hypertension: heart disease, stroke, chronic kidney disease, cognitive impairment, and premature death.

Prediabetes

Twenty-eight million or an estimated 11 percent of the general adult population in the U.S. have diabetes. Disproportionally high rates are found among American Indians/Alaska Natives (14.5 percent), non-Hispanic Blacks (12.1 percent) and people of Hispanic origin (11.8 percent). The majority of these adults have type 2 diabetes and experience higher rates of negative outcomes associated with the disease.[45]

Given the burden of diabetes among people from racial and ethnic minority groups in the U.S., there is a vital need to focus on primary prevention to address the current and projected growth of new cases of diabetes among groups with higher risks of negative health outcomes. Thirty-four percent of the U.S. population has prediabetes, with a disproportionate burden among these historically marginalized groups.

The AMA recommends that EHBs include coverage for all evidence-based screening tests for prediabetes and all evidence-based lifestyle change program interventions. These recommendations are supported by the National Clinical Care Commission in its final report to Congress, "Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications."[46]

[45] Centers for Disease Control and Prevention. National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed January 22, 2023.

[46] Report to Congress. (n.d.). Retrieved January 22, 2023, from https://health.gov/about-odphp/committees-workgroups/national-clinical-care-commission/report-congress.

The United States Preventive Services Task Force (USPSTF) recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. The screening tests for prediabetes are the same as diabetes: fasting plasma glucose, or HbA1c, or with an oral glucose tolerance test. But Medicare and other public and commercial plans do not cover HbA1c.

It further recommends clinicians refer their patients with prediabetes to effective preventive interventions such as the CDC's National Diabetes Prevention Program (DPP) lifestyle change program.[47] The ACA does not specifically mention coverage for the DPP lifestyle change program, but it does require that insurance companies cover preventive services recommended by the USPSTF without any cost sharing.

Therefore, coverage for the DPP lifestyle change program would depend on the specific plan and the state in which it is offered. Many insurance plans do cover the DPP lifestyle change program, but coverage varies from plan to plan and from state to state, leaving many patients with limited or no access to this evidence-based treatment that has been shown to reduce the risk of developing type 2 diabetes by 58 percent.

Obesity

The AMA declared obesity a disease in 2013. Since then, rates of obesity have steadily increased, with higher prevalence rates among historically marginalized populations. Forty-nine percent of Non-Hispanic Black adults have obesity, followed by 45.6 percent of Hispanic adults compared to 41.4 percent of Non-Hispanic White adults. A Harvard study projects that by 2030 the prevalence of obesity will rise to 50 percent nationally with certain historically marginalized groups, specifically African American and Hispanic women, having much higher rates than other groups.

The latest science on obesity has found a genetic component resulting in excessive accumulation of body fat. Genetics combined with structural inequities contribute to increases in the rates of obesity. While rates of obesity continue to rise, the good news is that treatment options for people with obesity have advanced to include medications and surgical interventions.

Unfortunately, many individuals with obesity lack access to the full continuum of care of evidence-based obesity treatment modalities such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions. The AMA is concerned that CMS categorizes obesity as a condition of overeating. This position ignores the latest medical evidence on genetics, hormone abnormalities, and the impact of certain medications on weight gain. This discriminatory language is a barrier to changes in the EHB. The AMA recommends that coverage of all evidence-based obesity treatments be considered essential. These include:

- Anti-obesity medications (AOM)
    - There has been tremendous advancement in medications since passage of the ACA with the FDA approving several AOMs throughout the last decade.
    - The use of AOMs is recommended by clinical guidelines establishing medical care.

[47] US Preventive Services Taskforce. (2021, August 24). Prediabetes and type 2 diabetes: Screening. Recommendation: Prediabetes and Type 2 Diabetes: Screening | United States Preventive Services Taskforce. Retrieved January 22, 2023, from https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.

- Metabolic and bariatric surgery

    - Metabolic and bariatric surgery is already widely covered by Medicare, TRICARE, the Federal Employees Health Benefits program, and nearly every State Medicaid and State employee plan. Despite this broad coverage and the significant evidence surrounding the effectiveness and safety of this treatment avenue, less than half of state EHB benchmark plans cover treatment for bariatric surgery.

- Intensive behavioral therapy services

    - Obesity is a multifactorial condition and requires a comprehensive treatment plan to promote sustained weight loss.

Drug Classification

The AMA believes it is useful for CMS to consider different medication lists for utilization of the EHB to continuously improve patient access to evidence-based medications. The current utilization of the USP Model Guidelines (MG) is limited by less frequent updating, and thus, newer agents are often excluded, limiting access to care for patients and the ability of physicians to make up-to-date, patient-centered decisions. Alternative lists include the American Hospital Formulary Service (AHFS) and the 2017 USP Drug Classification (DC). Other not-for-profit lists/classifications of medications do not exist or are incomplete. The AHFS listing is limited and if used would require significant adjustment to the current system, leaving many patients potentially without chronic medications. The USP DC is broader than the USP MG with more classifications, particularly of newer classes of medications. Further, this list is updated on an annual basis by a large stakeholder group. By switching to the USP DC, physicians would have a larger prescribing capability with the most modern listing of medications.

We would also like to note that the current EHB requirement of covering one drug per class may leave patients without coverage when there are drug shortages, which have occurred repeatedly during the COVID-19 PHE. CMS should consider covering at least two drugs per class or at least a pathway for coverage in drug shortages as a way to ensure continued access to care.

Thank you for considering our comments. We look forward to continuing to work with CMS as the agency considers all of the comments submitted and decides whether to move forward with a proposed rule to update the EHB. If you have any questions, please feel free to contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or (202) 789-7409.

Sincerely,

James L. Madara, MD