January 30, 2023

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

Re: Request for Information on Essential Health Benefits

Dear Secretary Becerra:

Thank you for the opportunity to provide comments to inform future rulemaking on the essential health benefits (EHB) requirement of the Affordable Care Act (ACA). We greatly appreciate your ongoing efforts to ensure the effective implementation of the patient protections and consumer-focused policies of the ACA, of which the EHB are a critical part.

The undersigned organizations represent millions of patients and consumers facing serious, acute and chronic health conditions across the country, including individuals who rely on the patient protections provided under the ACA. Our organizations have a unique perspective on what patients need to prevent disease, cure illness and manage chronic health conditions. Our breadth enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion.

In March 2017, our organizations agreed upon three overarching principles[1] to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit package.

The ACA's standards obligating insurers to cover all essential health benefits are of fundamental importance to the patients we represent. We thank the Department for its commitment to ensuring access to comprehensive coverage and preventing discrimination in benefit design. As many of our organizations noted in our September 2022 letter to the Department,[2] we recommend the Department continue to use its broad authority under the ACA to update and strengthen EHB standards to ensure plans cover all of the benefits and services patients need. We are therefore pleased the Department is seeking comments on that authority and other aspects of EHB, and we ask that you consider the following comments in response to the questions raised in the Request for Information (RFI).

Benefit Descriptions in EHB-benchmark Plan Documents

We agree with the Department's assessment that states' EHB-benchmark plan documents can describe benefits differently and without clear and complete information on the benefits covered in each of the 10 categories. We therefore support requiring greater consistency and detail in the information states submit for their EHB-benchmark plans. However, we would strongly oppose any effort to make greater standardization a prerequisite for the Department fulfilling its obligation to periodically review and update the EHB. While the current state of benchmark plan documents may, in fact, make it more difficult to reliably compare state benchmark plans, that cannot stand in the way of the Department beginning the urgent and statutorily required work of considering needed updates to the EHB.

Furthermore, we strongly caution the Department against concluding that a lack of consumer complaints about exclusions or claims denials is evidence of effective enforcement by states. Nor do we find a sufficient basis for concluding that plans subject to EHB requirements are not excluding services that are generally understood to be covered regardless of their specific inclusion in the relevant EHB-benchmark plan document. Few consumers are aware of how to report a complaint to their state department of insurance, and fewer still take the steps to do so.

Rather than conclude enforcement is sufficient and exclusions don't occur, we ask the Department to ensure that significant resources are devoted to enforcing existing EHB standards. This includes timely oversight in the states in which the Department directly enforces ACA protections. But, critically, it also includes increased support for the states that are serving as primary regulators *and for residents of all states* who, understandably, may not know where to go to get help for a problem with their ACA-compliant coverage. The Department should more fully realize a "no wrong door" approach for consumers by working with state partners to make it easier for consumers to figure out who to contact, and providing smooth transfers from one agency to another, for people who initially seek help in the wrong place.

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[1] Consensus Health Reform Principles. Available at: https://www.lung.org/getmedia/0912cd7f-c2f9-4112-aaa6-f54d690d6e65/ppc-coalition-principles-final.pdf.

[2] Letter to Secretary Becerra, September 13, 2022. Available at: https://www.lung.org/getmedia/a6911345-2b55-4182-a4dc-be8c69c1f4ee/NBPP-Priorities-Letter-9-13-22-(FINAL).

Review of EHB

The ACA directs HHS to periodically review the EHB framework. Under the statute, this review must include a report to Congress and the public that contains, among other things, assessments of (1) whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost; and (2) whether EHB must be modified or updated to account for changes in medical evidence or scientific advancement. These provisions of the ACA also explicitly charge the Department with the task of updating benefit requirements to address any gaps in access to coverage or changes in the evidence base that are identified in these reviews. The state benchmark process currently relies on benefit designs that are more than five years old and there are numerous areas in which benefit standards need to be reassessed and likely updated. Further, in the absence of HHS fulfilling its statutory obligation to review and update the EHB, the task falls to states to update their benchmark plans to respond to changing coverage and public health needs, but doing so puts states at risk of incurring the costs of these updates.[3]

In order to conduct a thorough and regular review, HHS should establish a process that is evidence-based, transparent, operates with clearly articulated timeframes for reviewing and reporting, allows for public input, and includes consumer and patient representatives. Such a review would identify barriers to accessing services due to coverage and cost, changes in medical evidence and scientific advancement, and any gaps in coverage for needed services. Below we offer comments on specific areas raised in the RFI.

Barriers of Accessing Services Due to Coverage or Cost

Role of Telehealth

Our organizations believe telehealth can and should be used to increase patient access to care. For example, telehealth has been utilized by individuals to receive mental health services; according to a GAO report, beneficiaries reported feeling more comfortable accessing behavioral health services at home by telehealth, and behavioral health services were among the most commonly delivered via telehealth in the first year of the pandemic.[4] We ask that HHS keep in mind that network provider access through telehealth should supplement not supplant network provider access to in-person visits. In all cases, consumers must retain the right and ability to choose between receiving care in-person or via telehealth. We also note that audio-only visits have been important to expand access to individuals who lack the broadband or devices needed for video-enabled visits. However, access to video-enabled visits has not been equitable, and for some patients, audio-only visits may not provide care in an optimal clinical setting.[5]

Cost and Utilization

While utilization management can help act as a safeguard for patients receiving appropriate care in an appropriate setting, it can often act as a barrier to necessary care. A recent report from the HHS Office of the Inspector General found that some Medicare Advantage plans used prior authorization to deny

[3] See 45 CFR §155.170

[4] Government Accountability Office, "Medicaid: CMS Should Assess Effect of Increased Telehealth Use on Beneficiaries' Quality of Care," GAO-22-104700, Mar. 31, 2022.

[5] U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, "National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services," Feb. 1, 2022.

beneficiaries access to medically necessary care.[6] Data for marketplace enrollees show that, on average, 17 percent of claims for in-network services were denied for reasons that include being found not medically necessary or for failure to obtain prior authorization or a referral.[7] In reviewing EHB, we urge the Department to ensure any utilization management is grounded in medical and scientific guidelines and is not used as a tool to restrict access to EHB. EHB's promise of providing access to a comprehensive set of benefits will be seriously undermined if insurers are able to use plan rules and care review programs to limit access to those services.

Changes in Medical Evidence and Scientific Advancement

Changes Since 2014

The RFI includes discussion of two advances in medicine since 2014 – a now-widely used dental treatment not available in 2014, and a greater reliance on doulas to improve maternal and newborn health outcomes. A systematic, evidence-based review would surely identify other advances in care and medicine that should be included in any updated EHB. One example we would urge the Department to consider is biomarker testing and genomic sequencing as an update to the scope of the laboratory services category. Developments in precision medicine over the past decade have greatly expanded the need for comprehensive biomarker testing. For example, biomarker testing allows doctors to identify abnormalities in a cancer cell's DNA and determine the best course of treatment for cancer patients. Studies show that cancer patients that have access to biomarker testing and are thus able to receive targeted therapy treatments have better overall chances of survival.[8] However, coverage in most healthcare plans has been found to be more restrictive than the National Comprehensive Cancer Network's guidelines for biomarker testing.[9] Because biomarker testing is not included in the current benchmark documents, there is no clear guidance for plans on coverage of this important medical advancement. The Department should consider reviewing the evolving evidence proving the clinical utility of biomarker testing across disease states and provide additional guidance on the scope of insurers' coverage requirements under the laboratory services category of EHB.

Advancing Health Equity

Here, too, a regular review of EHB is critical to identify advances in health equity that should be incorporated into EHB. To this end, we urge the Department to consider the role of algorithms in limiting care to certain populations. Many clinical algorithms, including those that assess risk of disease, dictate that Black patients, in particular, must be more ill than white patients before they can receive treatment for a range of life-threatening conditions, including for kidney disease, heart failure, and pregnancy-related complications. There are also clinical algorithms that may result in discrimination against individuals with disabilities and older adults. It will also be critical to ensure access to appropriate language services and other accommodations that make services available to all, regardless of preferred language or ability. In providing EHB, insurers must be held to strong standards under

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[6] U.S. Dept. of Health and Human Services, Office of the Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," Apr. 2022.

[7] Karen Pollitz and Matthew Rae, "Claims Denials and Appeals in ACA Marketplace Plans in 2020," KFF, Jul. 5, 2022.

[8] Howlader N, Forjaz G, Mooradian MJ, Meza R, Kong CY, Cronin KA, Mariotto AB, Lowy DR, Feuer EJ. The Effect of Advances in Lung-Cancer Treatment on Population Mortality. N Engl J Med. 2020 Aug 13;383(7):640-649. doi: 10.1056/NEJMoa1916623.

[9] Wong WB, Anina D, Lin CW, Adams DV. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. Per Med. 2022 May;19(3):171-180. Available at: https://www.futuremedicine.com/doi/full/10.2217/pme-2021-0174.

section 1557. Many of our organizations offered comments on those protections in our comments to the proposed rule last Fall.[10]

Addressing Gaps in Coverage

We believe strongly that the Department must obtain data from insurers to identify gaps in coverage rather than put the burden on consumers to identify and report those gaps. The Department's claims data for marketplace enrollees is one potential indicator of gaps in coverage: an average of 16 percent of claims were denied in 2020 as an excluded service.[11] As noted above, few consumers know to complain to state or federal regulators about problems with their health coverage, making complaints alone a poor indicator of any problem, let alone gaps in coverage. In addition, marketplace enrollees appealed only 0.1 percent of denied claims – further evidence that consumers either don't know about their options for resolving problems with their health coverage, or don't have the resources to pursue them.[12]

Below we offer comment on specific areas raised in the RFI.

Habilitative and Rehabilitative Services and Devices

Plans subject to EHB cannot impose a single, combined limit on habilitative and rehabilitative services and devices and, if limits are used, those that apply to habilitative services and devices cannot be less favorable than those that apply to rehabilitation. These are important protections, yet, there is insufficient data on service use to determine compliance with the letter and spirit of the rules.[13] In addition, it appears that the structure of benefit limits, which are often applicable to a specified time period (e.g., the calendar year), should be revisited. We suggest that such limits, if used at all, should be tied to a particular condition or episode of care, to ensure that patients with multiple conditions can access care sufficient to address their multiple needs.

Pediatric Services

The benchmark process preferences plans focused on the health needs of adults and there has been significant variation across state EHB benchmarks in the coverage of benefits and services for children specifically.[14] With the expiration of COVID-era Medicaid continuous coverage requirements, we expect many families will lose Medicaid, and its robust Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) pediatric benefit, and enroll in marketplace coverage. These transitions will exacerbate the risks posed by gaps in the EHB pediatric services benefit and illustrate why the current standard should promptly be reassessed and, if necessary, revised.

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[10] Letter to Director Fontes Rainer re Section 1557, October 3, 2022. Available at: https://www.lung.org/getmedia/ed541fc1-0142-407f-90e0-982ecc7f406d/Health-Partners-Section-1557-Comments-Final.

[11] Karen Pollitz and Matthew Rae, "Claims Denials and Appeals in ACA Marketplace Plans in 2020," KFF, J. ul. 5, 2022.

[12] Ibid.

[13] Letter from Habilitative Benefits Coalition to Administrator Brooks-LaSure. January 27, 2022. Available at https://habcoalition.files.wordpress.com/2022/02/hab-comments-on-2023-proposed-nbpp.pdf.

[14] Grace AM, et al., The ACA's Pediatric Essential Health Benefit has Resulted in a State-by-State Patchwork of Coverage with Exclusions. Health Affairs. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0743. Published Dec. 2014.

Other EHB Categories

The Department seeks comment on whether EHB should be updated to require coverage of behavioral health crisis services. Given the growing and substantial need for mental health and substance use disorder services and the recent launch of the 988 Suicide and Crisis Hotline nationwide, we believe it would be a mistake to not require coverage of these services in EHB.

Preventive services provided at no cost to consumers are one of the most widely used and important benefits. Yet uneven enforcement and inadequate guidance limits access to some expert-recommended services and treatments. For example, reports, as recent as 2020, have shown that tobacco cessation treatments are not consistently covered without cost-sharing in state exchanges.[15] This report also found many plans in state exchanges did not provide adequate information to determine what treatments were covered, which is a barrier to access in and of itself. We therefore urge the Department to strengthen enforcement and provide clearer guidance to ensure robust coverage of preventive services without cost-sharing.

Finally, the lack of clarity around chronic disease management makes it difficult to determine whether patients are receiving the support they need. It is often unclear what types of services are being covered within this category and whether plans are covering them for a comprehensive range of chronic diseases. We therefore urge the Department to set – and strongly enforce – standards for what must be covered for this category of EHB.

Coverage of Prescription Drugs as EHB

Plans currently satisfy EHB standards for prescription drugs if, among other things, they cover the greater of one drug per U.S. Pharmacopeia Medicare Model Guidelines (USP MMG) class and category or the number of such drugs included in the state's benchmark plan. This standard has not been updated since the EHB rules came into effect in 2014 and has proven to be inadequate to the needs of many patients we represent. Additionally, some medications on which our patients rely — including, for example, most drugs that treat bleeding disorders, and many cancer and primary immune deficiency drugs — are not part of the USP MMG classifications system, which is used to classify Medicare Part D drugs but does not include Part B drugs. This can make it effectively impossible for a consumer to determine whether a plan provides adequate coverage for their needs.

Our organizations support transitioning to the USP Drug Classification (USP DC) system, with the recognition that this will not be sufficient in addressing all of the challenges we have identified. The USP DC helps address some of the shortcomings of the USP MMG, as it includes drugs covered under Medicare Part B, has many more categories of drugs than USP MMG, and is updated more frequently than USP MMG. If the Department decides to transition to USP DC, it should consider codifying an annual process for review, feedback from consumers, and updates to ensure USP DC stays relevant to evolving needs. This change should also be paired with other reforms to bolster the prescription drug coverage standard. The Department could strengthen this standard by requiring coverage of a minimum of two drugs per USP class and category or the number covered by the benchmark plan, whichever is greater, as well as "all or substantially all" drugs in certain specified classes that are critical to vulnerable populations (similar to the approach adopted in Medicare Part D).

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[15] American Lung Association. Tobacco Cessation Coverage in State Exchanges – 2020. July 2020. Accessed at: https://www.lung.org/getmedia/fb9cdabf-7062-4e49-b86b-74754ab642eb/Exchange-Data-Report_FINAL_1

Substitution of EHB

Our organizations were pleased that the 2023 NBPP withdrew the flexibility for plans to substitute benefits between different EHB categories.[16] Although the Department says it has not received any information that a plan has ever substituted an EHB using that authority, our concerns about that flexibility remain. Given the recognized variability in EHB-benchmark plan detail on benefits covered and no real basis for assuming state enforcement is effective and adequate, we believe CMS would be wrong to conclude no plan is using the flexibility. If, as the RFI asks, there are changing public health concerns that might benefit from allowing insurers the flexibility to substitute benefits between different categories, the Secretary can update the EHB to require coverage of any benefits needed to respond to a public health concern or allow states to do so without triggering the requirement to defray the cost of additional benefits.

Conclusion

Thank you for considering this input on EHB. Please contact Hannah Green with the American Lung Association at hannah.green@lung.org with any questions. We look forward to partnering with you to advance affordable, accessible and adequate healthcare coverage for patients and consumers.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
American Kidney Fund
American Liver Foundation
American Lung Association
Alpha-1 Foundation
ALS Association
Arthritis Foundation
Cancer*Care*
Crohn's & Colitis Foundation
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Lupus Foundation of America
Muscular Dystrophy Association
National Alliance on Mental Illness
National Eczema Association
National Hemophilia Foundation
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Pulmonary Hypertension Association
Susan G. Komen
The AIDS Institute
The Leukemia & Lymphoma Society
The Mended Hearts, Inc.
WomenHeart: The National Coalition for Women with Heart Disease

[16] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27293-94 (reinstating prohibition on benefit substitution across EHB categories, codified at 45 C.F.R. § 156.115).