American Lung Association.

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) requirements of the Affordable Care Act (ACA).

The American Lung Association is the oldest voluntary public health association in the United States, representing the more than 34 million individuals living with lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

The ACA's EHB standards are vital for patients with and at risk for lung disease to access the comprehensive care that they need. The standards have expanded access to preventive services like lung cancer screening and tobacco cessation, prescription medications, habilitative and rehabilitative care like pulmonary rehabilitation, and many more important treatments and services. However, 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 updated.

In addition to the robust comments that we submitted with other patient advocacy organizations,[1] the Lung Association offers the following information on the challenges that many patients with and at risk for lung disease face related to essential health benefits and recommendations for improving patients' access to comprehensive, high-quality care.

Benefit Descriptions in EHB-Benchmark Plan Documents

The Department correctly acknowledges the variation in information available in EHB-benchmark plan documents across states. The lack of detail in many documents can make it difficult to determine whether and how key treatments and services for lung disease are covered. For example, pulmonary rehabilitation, part of evidence- and guidelines-based care, is an important program of education and exercise for patients with COPD and other lung diseases designed to improve lung function, reduce symptom severity and improve quality of life. The Lung Association's review of the current EHB-benchmark plan documents found that only about half mention pulmonary rehabilitation, and among those that do, plan documents still differ widely in the information provided related to visit limits and other coverage restrictions. The Lung Association would support requiring greater consistency and detail in the information states submit for their EHB-benchmark plans to better understand and compare coverage. However, these changes should not be a prerequisite for addressing many of the known gaps in the current EHB standards.

The RFI also states that "based on our discussions with States and a lack of consumer complaints about exclusions or claims denials, plans subject to EHB requirements do not appear to be excluding services that are generally understood to be covered, regardless of their specific inclusion in the relevant EHB-benchmark plan document." We disagree with this conclusion. Many patients do not know where to go to make a complaint or realize their rights to appeal coverage decisions. To better understand consumers' experience with EHB requirements, the Department should increase resources devoted to enforcement of EHB standards, improve consumer assistance so that more patients know where and how to receive help with their coverage, and collect data on denied claims and other metrics that can expose potential gaps in coverage.

Review of EHB

The Lung Association strongly urges the Department to conduct a review of the current EHB standards, as directed by the ACA. This process should be evidence-based, operate transparently with clearly articulated timeframes for reviewing and reporting, allow for public input and include patient representatives. A regularly scheduled review and update process would also help to identify advances in care that can improve health equity and should be incorporated into EHB.

Changes in Evidence and Advancement

The Department seeks comments on changes in medical evidence and scientific advancement that are not reflected in the current EHB-benchmark plans. Developments in precision medicine over the past decade have greatly expanded the need for comprehensive biomarker testing, which allows doctors to identify abnormalities in a cancer cell's DNA and determine the best course of treatment for lung cancer patients. Studies show that lung cancer patients that have access to biomarker testing and are thus able to receive targeted therapy treatments have better overall chances of survival.[2] However, coverage for biomarker testing in most healthcare plans has been found to be more restrictive than the National Comprehensive Cancer Network's guidelines.[3]

Because biomarker testing is not discussed in the current EHB-benchmark plan documents, there is no clear guidance for plans on coverage. Clarity around EHB standards for biomarker testing is particularly important for advancing health equity, given the disparities in current testing rates – for example, research shows that Black patients with non-small cell lung cancer are less likely to receive testing than white patients.[4] While there is clearly evidence for the Department to immediately provide additional guidance on the scope of insurers' coverage requirements for biomarker testing under the laboratory services category of EHB, this gap also underscores the need for a regular, systematic review to identify other advances in care and update EHB standards accordingly.

Gaps in Coverage for Chronic Conditions

The Department also seeks comments on gaps in coverage for those with chronic and lifetime conditions. One clear gap involves tobacco cessation. Plans subject to EHB standards must cover tobacco cessation interventions for non-pregnant adults, including both pharmacotherapy and behavioral interventions, which have received an "A" grade from the United States Preventive Services Task Force. These requirements were also clarified in sub-regulatory guidance from the Departments of Labor, Treasury and Health and Human Services in 2014. However, in 2020, the Lung Association found that tobacco cessation treatments are not consistently covered without cost-sharing in marketplace plans, which are all subject to EHB

requirements.[5] This report also found many plans in state marketplace plans did not provide adequate information to determine what treatments were covered, which is a barrier to access in and of itself. These gaps highlight the need for stronger enforcement of current EHB standards for preventive services.

Another gap in coverage for those with chronic and lifetime conditions involves chronic disease management. Our review of the current EHB-benchmark plan documents found little information available on the types of services included under chronic disease management and the health conditions for which disease management services are available. For example, disease management services for COPD are mentioned in just five states' EHB-benchmark plan documents. The Lung Association urges 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. These standards have not been updated since the EHB rules came into effect in 2014 and the Lung Association has heard from patients with lung disease that they struggle to access needed medications under the current standards. For example, patients shopping for plans through Healthcare.gov who filter their options by those that cover their prescriptions have found that they only have one option, greatly limiting their choice during the plan selection process. Patients have also reported only being able to obtain medications after multiple calls to an insurance company or after a provider intervened. Appeals processes can cost patients important time while waiting for the medication that they need to be approved, particularly for patients with life-threatening conditions like lung cancer. Patients without the resources or health literacy to navigate a complex administrative process may not even attempt an appeal, exacerbating health disparities.

Additionally, some medications on which our patients rely — including, for example, many cancer 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 patient to determine whether a plan provides adequate coverage for their needs.

These challenges demonstrate the need to update the EHB standards for prescription drugs. The Lung Association recommends 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). The RFI also discusses transitioning to the USP Drug Classification (USP DC) system. The USP DC helps address some of the shortcomings of the USP MMG – as it includes drugs covered under Medicare Part B, and it has many more categories of drugs than USP MMG – but this transition alone would not ensure that patients with lung disease have access to a sufficient range of treatment options. 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, and this transition must be paired with other improvements to the prescription drug standards. A comprehensive approach is needed to help patients with lung

cancer, COPD and other lung diseases access the medications they need to stay healthy and manage their conditions.

Substitution of EHB

The Lung Association supported the changes in the 2023 Notice of Benefit and Payment Parameters withdrawing the flexibility for plans to substitute benefits between different EHB categories.[6] 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 the concerns raised above about the Department's conclusions that 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 the opportunity to provide these comments. The Lung Association plans to collect additional data on coverage of treatments and services for lung disease under the current EHB standards later this year and will share that information with the Department when available. We look forward to continuing to partner with you to advance quality, affordable healthcare for patients.

Sincerely,

Harold Wimmer

Harold Wimmer
President and CEO

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[1] Health Partner Letter to Secretary Becerra re: Essential Health Benefits, January 30, 2023. Available at: https://www.lung.org/policy-advocacy/advocacy-archive.

[2] 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.

[3] 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.

[4] Presley CJ, PR, Chiang AC, Longtine JA, Adelson KB, Herbst RS, Nussbaum NC, Sorg R, Abernethy AP, Agarwala V, and Gross CP. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. Journal of Clinical Oncology 2017 35:15_suppl, 6563-6563.

[5] 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

[6] Letter to Secretary Becerra from the American Lung Association and patient advocacy organizations, January 27, 2022. Available at: https://www.lung.org/getmedia/aef95452-ad4d-4a9c-b6bf-900b33d0e947/012722-PPC-2023-NBPP-Comments-FINAL.