Harold P. Wimmer
National President and
CEO

July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The American Lung Association appreciates the opportunity to comment on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.*

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease, and serves as the voice of the over 32 million Americans suffering from lung disease.

The Lung Association is encouraged by the U.S. Department of Health and Human Services' (HHS) focus on lowering drug prices and reducing out-of-pocket (OOP) costs for patients. High drug prices are placing an enormous burden on lung disease patients. High out-of-pocket costs can cause patients to delay care or even skip treatment, worsening health outcomes.[1] Greater transparency is needed so patients can better understand their prescription drug coverage options and work with their providers to make appropriate treatment decisions. Addressing high out-of-pocket costs for patients is critical in improving the health of patients, and maintaining patient access must be prioritized in any proposed measures to lower drug costs. In order for the Lung Association to support changes, they must be consistent with our set of healthcare consensus principles, and ensure that coverage is affordable, accessible and adequate for patients.[2]

The Lung Association offers the following comments from its unique position as a voice for lung disease patients. These comments include numerous citations to supporting research, including links to the research for the benefit of HHS in reviewing our comments. We direct HHS to each of the studies cited and made available to the agency through active

hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the formal administrative record on this request for information for purposes of the Administrative Procedures Act.

Changes to the Protected Classes

The Lung Association is concerned with changes regarding the protected classes and their impact on patient's access to medications. The six protected classes were established to assure appropriate access to critical medications. Many of these drugs are not interchangeable and are prescribed in tailored combinations for each patient to meet the patient's needs. For example, lung cancer patients may need targeted therapy or immunotherapy to address their specific tumor. Relying on an appeals process for non-formulary treatments, which will place a great administrative burden on providers and patients, would cause delays in accessing treatments in a timely matter. An open and robust formulary is necessary so patients can access the treatments their provider believes are best for the patient sitting in front of them.

Specifically, the Lung Association opposes changes to the Part D formulary standards that would decrease the minimum number of drugs in a class or category from two to one. This would severely limit patient access and choice. Similarly, the Lung Association is concerned with the proposal to provide plans full flexibility to manage high-cost drugs without rebates or negotiated fixed prices in Part D, including the six protected classes. Providing Part D prescription plans this authority would allow plans to impose additional limits on the drugs they cover, and even remove drugs from the formulary, which would reduce patient access. The Lung Association is also concerned that treating drugs with price increases or drugs that do not provide discounts differently when determining the exceptions criteria for protected class drugs will negatively impact patient access to critical drugs. A drug price increase should not automatically allow it to be excluded from the six protected classes, penalizing patients relying on the drug to treat or manage their condition.

Allowing Part D plans to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug

The Lung Association opposes any proposal to allow formulary changes in Part D plans during the benefit year in response to price increases for sole source generic drugs. The drug formulary is a critical factor for patients when making decisions about selecting their plan for the year. Under this proposal, Part D plans could be allowed to remove drugs, change their benefit package or impose additional utilization management tools mid-year, creating confusion and instability for patients. These types of formulary changes could force patients who are managing their condition well on a certain drug to change their medication mid-year or forgo treatment altogether if they cannot afford the drug once it is moved to a higher formulary tier. Mid-year formulary changes allow Part D plans to implement further barriers in patients' access to the treatments they need.

For patients with asthma, this approach contradicts guidelines-based care. The National Heart, Lung, and Blood Institute's (NHLBI) Expert Panel Report 3 National Asthma Education and Prevention Program (NAEPP) Guidelines[3] recognizes that the most effective treatment for a patient is individualized and to achieve the best health outcomes, many treatments need to be covered.

Similarly, the United States Preventive Services Task Force (USPSTF) recognized the importance of individualized treatment in their 2015 Clinical Guidelines, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement*. The guidelines explicitly state, "The best and most effective combinations are those that are acceptable to and feasible for an individual patient; clinicians should consider the patient's specific medical history and preferences and offer and provide the combination that works best for the patient." This requires robust formulary coverage of cessation medications. Allowing Part D plans to restrict coverage would be counter to the clinical recommendation.

New Medicaid Demonstration Authority for Up to Five States

The Lung Association is concerned with the proposal for new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms built on private sector practices. Allowing states to determine their own drug formularies threatens patient access to necessary treatments. The Medicaid population is a vulnerable population without the option to shop around for health plans and as such, commercial insurance tools built only to contain costs are inappropriate for this population.

While the proposal does include an appeals process to obtain access to non-covered drugs based on medical need, reliance on an appeals process is prohibitive as patients would likely become delayed by bureaucratic requirements and red tape before possibly obtaining the drug they need. This process would be a barrier to patient access, especially for drugs that require timely administration. Patients with lung diseases like asthma and COPD, who need their medication to breathe, cannot simply wait through the appeals process for their medication. The appeals process adds unnecessary delays to patient access to necessary drugs and creates an avoidable administrative burden.

Establishment of a Beneficiary Out-of-Pocket Maximum in the Catastrophic Phase

Although Part D coverage has improved affordability of medications for Medicare beneficiaries, many patients face high out-of-pocket (OOP) costs. Patients who enter the catastrophic phase often have very high-priced medications, and even paying five percent coinsurance in this phase still translates to significant OOP costs. Establishing a beneficiary OOP maximum in the catastrophic phase of Part D would be beneficial for patients with high drug spending, especially

those with chronic diseases who rely on continuous treatment. Furthermore, an analysis by Avalere found that reducing Part D OOP costs for patients increases the number of prescriptions filled and improves access and adherence, thereby improving health outcomes and reducing overall medical spending.[4]

It is important that the OOP maximum is established at an affordable level and must be indexed to reflect the average Medicare enrollee's income. If the OOP maximum is set too high, many patients would not see an improvement. Thus, the Lung Association encourages HHS to conduct studies on OOP maximums to determine the level of OOP costs that would be most helpful in ensuring medications are affordable for patients. In addition, the Lung Association encourages HHS to explore the potential of monthly out-of-pocket (MOOP) maximums, which cap maximum monthly costs instead of annual costs. Some beneficiaries who rely on multiple expensive medications would reach an annual cap quickly, creating a high financial burden in a short amount of time. A monthly OOP cap could help to spread these costs throughout the year, and is an option to be examined further.

Eliminating Cost-Sharing on Generic Drugs for Part D Low-Income Subsidy (LIS) Beneficiaries

The Lung Association supports the elimination of cost-sharing for generic drugs for LIS beneficiaries, as it could help many patients access the medication they need. Cost-sharing, even at levels as low as $1 to $5, is a barrier for many low-income patients, who end up reducing their use of care and necessary services.[5] Eliminating cost-sharing for generic drugs would allow LIS beneficiaries to access medications without having to trade-off other necessities, such as food. It would also help patients better adhere to their medication and ultimately improving health outcomes. Furthermore, eliminating cost-sharing for generics will encourage beneficiaries to choose generics, driving people to lower cost drugs and saving Medicare money. Still, while eliminating cost-sharing for generics in the LIS population will improve access and health outcomes for some patients, the proposal will not be sufficient for LIS beneficiaries who need the brand version of the drug or drugs where no generic is available.

Directing CMS to Develop Demonstration Projects to Test Innovative Ways to Encourage Value-Based Care and Lower Drug Prices

Innovative models, such as value-based care, offer approaches to delivering care that can benefit patients. However, any value-based payment model must prioritize patients' treatment preferences and the value must be defined by outcomes that matter to the patient. Simply put, cost cannot be the sole indicator of value. Patients value different outcomes and if variations in patient values are not incorporated into outcome quality measures, patients may be penalized for their treatment decision.

Any demonstration project testing value-based care and efforts to lower drug prices must be patient-centered and improve health outcomes without reducing access. Models such as indication-based pricing must be carefully evaluated and the Lung Association urges caution at the adoption of such models. Clinical effectiveness varies among patients with different health conditions, and even among patients with the same health condition. As with the assessment of value-based payment models, indication-based pricing must be tailored to personalized treatment and patient needs and values; otherwise, reimbursement could disincentivize patient-centered treatment and lead to sub-optimal health outcomes. The Lung Association encourages HHS to conduct studies to evaluate how indication-based pricing proposals would impact patients before adoption is considered.

Moving Particular Drugs or Classes of Drugs in Part B to Part D

The Lung Association urges that the Medicare program not shift any drugs from Part B to Part D due to strong concerns about increases in patient OOP costs and patient safety. While there may be cost savings for the Medicare program by moving drugs from Part B to Part D, OOP costs and Part D premiums will likely increase for many patients. An Avalere study found that beneficiaries' OOP costs for new cancer therapies cost nearly 33 percent more in Part D than those in Part B, likely due to supplemental coverage in Part B that helps with OOP costs.[6] Similarly, an Acumen study found that moving oral cancer drugs from Part B to Part D will cause beneficiaries to pay an average of $391 more at each point of sale.[7] The proposed change of moving drugs from Part B to Part D simply shifts the cost from the Medicare program to Medicare beneficiaries, and does not truly address the issue of high drug prices or reduce OOP costs for patients.

Moving drugs from Part B to Part D also raises concerns about safety and timely administration of critical drugs. Part B drugs, including infusible and injectable drugs administered in physician offices and hospital outpatient departments, rely on complex provider administration and often require special storage and handling. Drugs that get moved from Part B to Part D would need to be picked up by patients at the pharmacy and brought to their provider for administration. Patients will have the burden of following the special storage and handling requirements for those drugs and providers would be forced to make judgements about the length of time the medication has been in transit, if the medication has been stored in the right temperature and if the medication has been tampered with. Oral anti-cancer drugs, such as those for lung cancer, and drugs requiring the use of durable medical equipment, such as asthma drugs, are among the drugs that could be affected by this change. For lung disease patients, these questions of patient safety can be a matter of being able to breathe.

Pharmacy Gag Clauses

The Lung Association supports ending the use of pharmacy gag clauses. This would be a promising step towards communicating costs to consumers. Patients need timely and relevant information regarding their prescription medication costs so they can make the best decisions regarding their drug spending. It is important that any changes to communicate costs to patients are tested by consumers to show that these approaches are effective and that patient groups are consulted to ensure that the patient perspective is considered.

Site Neutrality for Physician Administered Drugs, and Between Inpatient and Outpatient Settings

The Lung Association is concerned that the proposal for site neutral payments for physician administered drugs between inpatient and outpatient settings could decrease patient access. While providing physician administered drugs at outpatient sites should be encouraged, there are times when other locations of care are appropriate. Patients need to be able to access different sites of care based on their unique needs. Decreasing reimbursement in impatient settings may decrease the number of outpatient sites that are willing to administer drugs, which could shrink provider networks and restrict patient access to timely care.

The American Lung Association appreciates the opportunity to submit comments on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.* The Lung Association stands ready to work with policymakers to ensure that any changes protect patient access to care, increase affordability and improve health outcomes.

Sincerely,

Harold P. Wimmer
National President and CEO

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