AMERICAN LUNG ASSOCIATION.

Harold P. Wimmer
National President and CEO

December 31, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: International Price Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The American Lung Association appreciates the opportunity to comment on the advance notice of proposed rulemaking (ANPRM) regarding the International Price Index Model for Medicare Part B Drugs.

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy. The Lung Association works on behalf of the 33 million Americans living with lung diseases.

The Lung Association understands that 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] At the same time, any policy changes aimed at reducing prescription drug prices must also ensure that patients are able to access to the medications that they need. In order for the Lung Association to support policy 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 ANPRM would launch a mandatory nationwide demonstration to replace the current reimbursement model for medications administered under the Medicare Part B program. This new structure could have significant implications for patients' access to medications, but many key questions and concerns remain unaddressed in the ANPRM that will influence exactly how the proposal impacts patients. Given the questions and concerns this ANPRM raises, the Lung Association cannot support this effort as currently described and urges the Department not to move forward with a notice of proposed rulemaking unless these questions and concerns are resolved.

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Importance of Part B Medications for Lung Disease Patients

For decades, lung cancer patients have had little hope, but the era of precision medicine has transformed the lives of many patients with lung cancer. Over the last 10 to 15 years, the development of targeted therapies has extended the lives of patients with specific mutations in their cancer and immunotherapies have stimulated the body's ability to better attack and even destroy the cancer. For example, angiogenesis inhibitors have helped to treat advanced non-small cell lung cancer (NSCLC) by blocking the growth of new blood vessels that allow cancer to develop and spread. Additionally, immunotherapies that block the PD-1 protein and thereby boost the immune response against cancer cells have been used to help people with certain types of NSCLC whose cancer has started growing again after chemotherapy and other drug treatments. It is vital that patients have access to the range of innovative therapies available to treat lung cancer – many of which are covered under Part B and could be impacted by the ANPRM – so they can obtain the treatments that their doctors decide are best for them. The rate of development of these new therapies means the next drug that comes along can be used to extend or even save patients' lives when the cancer recurs or progresses. In 2018 alone, the Food and Drug Administration approved ten new therapies for the treatment of lung cancer. It is essential that patients have access to these treatments and that any new payment models continue to incentive the development of new therapies.

Access to therapies covered through Part B is critical for patients with other lung diseases as well. Patients with uncontrolled asthma struggle with recurrent flares and hospitalizations, increasing healthcare costs and contributing to lost productivity. These patients need access to the vast array of inhaled medications and more significantly, the newer biologic medications that can reduce the inflammation in the airways and are not only alleviating symptoms but starting to make strides in actually treating and impacting the underlying disease process. Many of these biologic medications are also covered through Part B.

The ANPRM states that CMS plans to begin the model with single source drugs and biologic medications, including most of the medications that appeared in the Department's recent report, "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures." This report discussed multiple medications that are critical for lung disease patients with lung cancer or asthma, including the types of therapies mentioned above. The Lung Association urges CMS to release a list of the specific medications that would be included under the proposed model so that we can fully assess the impact on lung disease patients.

Impact of ANPRM on Access to Medications for Patients

The demonstration would build upon a Competitive Acquisition Program (CAP) authorized under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. CMS would contract with private sector vendors who would then supply medications to providers in Medicare Part B. The number of vendors that participate in the demonstration will have important implications for patients. When CMS originally implemented CAP as a voluntary program, just one vendor and very few physicians signed up to participate, and CMS ultimately ended the program.[3] If the new demonstration has similar problems attracting qualified vendors, providers may

struggle to supply the medications their patients need, potentially delaying patients' treatment and jeopardizing their health.

The authorities that vendors will have under the demonstration also need to be clarified, as these have important implications for lung disease patients. Since Medicare Part B is legally required to cover any medications that are "reasonable and necessary for the diagnosis or treatment of illness or injury," it is unclear what would happen if vendors and pharmaceutical companies are unable to reach an agreement regarding prices under the demonstration.[4] The Lung Association is particularly concerned that CMS may allow vendors to implement utilization management tools as part of their negotiations. This change would increase barriers like prior authorization and step therapy that limit patients' access to the evidence-based care that they need to manage lung diseases. The Lung Association urges CMS to clarify whether vendors will be allowed to use utilization management tools and if so, how those tools are to be used, under the demonstration.

The demonstration would also have important implications for providers that could affect patients as well. Changing to a new payment model that involves negotiating with vendors could introduce new costs and administration burdens for providers. Certain providers may also experience reduced reimbursement for administering drugs under the proposed payment formula. These changes could lead providers to leave the Medicare Part B program, potentially limiting patients' choice of physicians and forcing them to travel further or to more expensive facilities for needed care.

Additionally, the ANPRM states that CMS is considering a bonus pool for model participants for "prescribing lower-cost drugs or practicing evidence-based utilization."[5] The Lung Association is concerned that these financial incentives could lead providers to choose medications that may not be the optimal choice for their patients. Clinical care for lung disease patients should follow evidence-based guidelines including the National Asthma Education and Prevention Program (NAEPP) guidelines, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines and the National Comprehensive Cancer Network (NCCN) for lung cancer treatment. The Lung Association would oppose any incentives that could lead providers to deviate from these evidence-based guidelines.

The demonstration could also impact patients' cost sharing for their medications. If the model is successful in reducing prices for certain drugs, patients' cost sharing for these medications could be reduced as well. However, since 81 percent of traditional Medicare enrollees have supplemental coverage, many patients may not actually see a change in their out-of-pocket costs.[6] Additionally, the ANPRM states that physicians would still collect any cost-sharing payments from patients under the demonstration. Yet it is unclear where or how patients could make appeals regarding their cost-sharing payments given the new role for vendors in the demonstration. It is critical that lung disease patients have a clear, simple and timely pathway for any appeals regarding the cost of and access to their medications.

CMS proposes to roll out the demonstration nationwide, with about 50 percent of the country required to use the new payment methodology and 50 percent in a control group. The Lung Association is concerned about the size and scope of the model given its potential to change patients' access to medications. If CMS decides to move forward with a notice of proposed rulemaking, the Lung Association would encourage the agency to consider piloting this demonstration on a much smaller scale where any implications for patients' access to medications can be identified and remediated before expanding the number of patients under the demonstration.

Finally, the ANPRM states that CMS would implement a monitoring program to assess beneficiary outcomes throughout the demonstration. The Lung Association agrees that such monitoring would be critical to track patients' access to and quality of care, as well as associated health outcomes. This monitoring must be comprehensive, well documented, and tracked in real time in order to provide meaningful feedback on patients' experiences. The Lung Association requests that, before CMS moves forward with a notice of proposed rulemaking, a robust monitoring plan be released with an opportunity for public comment to collect informed input on the plan and its implications for patients and other stakeholders.

Conclusion

Given the questions and concerns this ANPRM raises, the Lung Association cannot support this effort as currently described and urges the Department not to move forward with a notice of proposed rulemaking unless these questions and concerns are resolved. The Lung Association stands ready to work with CMS to ensure that any changes regarding prescription drug prices protect patient access to care, increase affordability and improve health outcomes. Thank you for the opportunity to provide comments on this proposal.

Sincerely,

Harold P. Wimmer
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[1] Doshi, J. A., Li, P., Huo, H., Pettit, A.R., & Armstrong, K.A. (2018). Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. Journal of Clinical Oncology, 36(5), 476-482. doi:10.1200/jco.2017.74.5091

[2] Consensus Healthcare Reform Principles. Retrieved from http://www.lung.org/assets/documents/advocacy-archive/consensus-healthcare-reform.pdf

[3] Sachs, Rachel. Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B. October 26, 2018. Accessed at: https://www.healthaffairs.org/do/10.1377/hblog20181026.360332/full/

[4] Sachs, Rachel. Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B. October 26, 2018. Accessed at: https://www.healthaffairs.org/do/10.1377/hblog20181026.360332/full/
[5] Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). October 30, 2018. Accessed at: https://www.regulations.gov/document?D=CMS-2018-0132-0001
[6] Kaiser Family Foundation. An Overview of Medicare. November 22, 2017. Accessed at: https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/