AMERICAN LUNG ASSOCIATION.

Harold P. Wimmer
National President and CEO

January 25, 2019

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

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The American Lung Association appreciates the opportunity to comment on the notice of proposed rulemaking regarding Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses.

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 35 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 and that new treatments continue to be developed. 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 proposed rule would make a number of changes to prescription drug coverage through Medicare Advantage (MA) and Medicare Part D. While the Lung Association supports the prohibition against gag clauses in pharmacy contracts and efforts to improve the transparency of how much consumers pay for their prescription drugs, a number of other policies in the proposed rule could jeopardize lung disease patients' access to prescription medications. The Lung Association therefore urges CMS not to finalize the proposed rule as currently drafted.

Advocacy Office:
1331 Pennsylvania Avenue NW, Suite 1425 North
Washington, DC 20004-1710
Ph: 202-785-3355 F: 202-452-1805

Corporate Office:
55 West Wacker Drive, Suite 1150 | Chicago, IL 60601
Ph: 312-801-7630 F: 202-452-1805 info@Lung.org

Providing Plan Flexibility to Manage Protected Classes

Medicare Part D currently requires plans to include all drugs within six protected classes on their formularies. These classes are critically important to lung disease patients, as they include antineoplastics for patients with lung cancer as well as immunosuppressants for individuals who receive lung transplants. Many of the drugs in the six protected classes 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 treat their specific tumor. Lung transplant recipients typically remain on a triple drug immune suppressant regimen and decisions about the choice of drugs need to be nuanced and individualized by the transplant physician based on how the transplant recipient is doing clinically and what drug toxicities or interactions are present. The Lung Association opposes the changes in the proposed rule related to the six protected classes because they could jeopardize lung disease patients' access to these treatments.

First, the proposed rule would allow plans to apply prior authorization and step therapy restrictions for patients newly starting a medication as well as for patients who are currently stable on a medication within the six protected classes. Restrictions like prior authorization can lead to delays in patients' access to necessary care and lead some patients to abandon treatment for their condition.[3] Expanding the use of prior authorization and step therapy in the six protected classes could therefore interrupt or prevent patients' access to the appropriate lung cancer and lung transplant medications, disruptions that could have life-threatening consequences for individuals with lung disease.

Medications in the six protected classes are extremely important for lung disease patients. Chuck B from Florida received a single lung transplant in January of 2017. He has idiopathic pulmonary fibrosis, a disease that results in scarring of the lungs. Since his transplant, his lung function has dramatically improved. His doctors constantly monitor Chuck's body's response to the treatments he's on and says it's taken years for doctors and researchers to "tinker around" with when to increase certain medications and to decrease others. He asks, "Why would you want to take a step backward?" by adding step therapy restrictions when the balancing act to protect his new lung already has life or death consequences.

The proposed rule would also allow Part D plans to exclude new formulations of medications in the protected classes from their formularies, even if the original formulation is discontinued. This change would clearly limit patients' access to innovative therapies. It is unacceptable that a lung cancer patient could be told that the treatment that is keeping them alive has a new formulation and is no longer covered. While manufacturers may discontinue a previous version of a medication to encourage use of a new, more expensive version recently brought to the market, patients should not be penalized for this change and lose access to a needed therapy.

Finally, the proposed rule would allow Part D plans to exclude medications in the protected classes from formularies if their wholesale acquisition cost price increases beyond the rate of the inflation. We are concerned that this change could limit lung disease patients' access to needed

medications and punish patients for pricing changes that are out of their control. The proposed rule also asks for comment on allowing plans to exclude all national drug codes (NDCs) associated with a protected class medication if one medication's price increase exceeds the threshold, as well as allowing plans to exclude all protected class medications from one manufacturer if the price increase of one medication from that manufacturer exceeds the threshold. Both of these policies would worsen the risk that lung disease patients lose their access to important medications.

While the Lung Association supports the goal of lowering prescription drug costs for patients and the federal government, the majority of prescriptions for medications for the six protected classes are already generic; for example, 76 percent of Part D prescriptions for antineoplastics and 79 percent of Part D prescriptions for immunosuppressants were for generic medications in 2016.[4] Additionally, the Administration's own proposal notes that there are limited opportunities for plans to make changes to their current management of antineoplastic, antiretrovirals and immunosuppressants due to the "narrower indications and complicating clinical criteria" for these medications.[5] Therefore, if plans were to make changes to the protected classes that resulted in cost savings, they would likely come at a cost to patients' health.

Overall, these changes to the protected classes will create a race to the bottom, where plans cover fewer and fewer medications in the protected classes and lung disease patients have limited or no choices to access the medications that they need to treat their lung cancer or ensure a successful lung transplant. These changes will likely have an even greater impact on vulnerable populations including individuals who qualify for the Low-Income Subsidy program, as these individuals already have a more limited ability to shop for plans if they want to make the most of their financial support.[6] The Lung Association therefore urges CMS not to finalize any changes to the six protected classes as part of the final rule.

Prohibition Against Gag Clauses in Pharmacy Contracts

The proposed rule would codify provisions from the Know the Lowest Price Act of 2018 that prohibit Part D plans from restricting their network pharmacies from informing enrollees that the cash price for a medication is lower than the amount patients would pay through their health insurance. 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.

E-Prescribing and the Part D Prescription Drug Program

The proposed rule would require Part D plans to implement an electronic real-time benefit tool (RTBT) capable of integrating with e-prescribing and electronic medical record systems to make beneficiary coverage and cost-sharing information visible at the point of prescribing. The Lung Association supports this effort to improve price transparency for both patients and prescribers. If CMS moves forward with this policy, the Lung Association urges CMS to ensure that the information included is easy to understand and will not create confusion for patients that could lead to treatment decisions that are not the most appropriate for patients' conditions.

Part D Explanation of Benefits

The proposed rule would require Part D plans to include new information about prescription drug prices in the explanation of benefits (EOB) provided to patients monthly detailing their utilization of their prescription drug benefits. The Lung Association supports the goal of increasing transparency about prescription drug costs for consumers. However, some of the proposed changes may have unintended consequences for lung disease patients. For example, including the percentage change in the negotiated prices of patients' medications on the EOB could cause unnecessary confusion, as this may or may not impact patients' out-of-pocket costs. Another proposed change would allow plans to list lower-cost therapeutic alternatives in the EOB, including medications that may be from a different class but indicated to treat the same condition. Decisions about which medication is most suitable for a patient should be based on evidence-based clinical guidelines and the judgement of a provider who knows that patient's individual needs. Including information about medications that are not therapeutically equivalent could therefore create confusion and to lead to changes in treatment that are not in the best interest of the patient. If CMS moves forward with this policy, the Lung Association again urges CMS to ensure that the information included is easy to understand and will not create confusion for patients or incentivize treatment decisions that could harm patients' health.

Medicare Advantage and Step Therapy for Part D Drugs

The proposed rule would codify changes that CMS announced in 2018 allowing MA plans to use step therapy for Part B medications when patients are newly starting a treatment. These medications include treatments that are critical for lung disease patients, such as immunotherapies used to treat lung cancer and biologic medications used to treat asthma. While the Lung Association appreciates the Administration's acknowledgement that an appeals process will be needed with timeframes applicable to Part D for coverage determinations, an appeals process will not be sufficient to protect lung disease patients' access to needed treatment.

As stated earlier related to use of step therapy for protected class drugs, step therapy can block patients' access to the appropriate treatments. The Administration's own rule cites studies showing that step therapy leads patients to discontinue treatment and can cause delays in care that ultimately lead to higher health costs.[7] 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, the National Comprehensive Cancer Network (NCCN) guidelines for lung cancer treatment and the American College of Chest Physicians guidelines for immunosuppressive drugs for lung disease and lung transplant recipients.[8] Additional restrictions like step therapy could impede access to guidelines-based care. The Lung Association therefore urges CMS not to finalize these changes in the proposed rule.

Conclusion

As currently drafted, certain policies in the proposed rule would restrict lung disease patients' access to needed medications, and the Lung Association urges CMS not to finalize the proposed rule in its current form. Thank you for the opportunity to provide comments.

Sincerely,

Harold P. Wimmer
National President and CEO

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

[3] American Medical Association, 2017 Prior Authorization Physician Survey, Feb. 2018. Accessed at: https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf.

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