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National President and  
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April 8, 2019

Aaron Zajic  
Office of Inspector General  
Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201

Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr.Zajic:

The American Lung Association appreciates the opportunity to comment on the notice of proposed rulemaking regarding the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.

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.<sup>1</sup> 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.<sup>2</sup>

The proposed rule would make a number of changes to the prescription drug rebate system for Medicare Part D and Medicaid managed care organizations (MCOs). The Lung Association believes the Administration's proposed changes to the safe harbor protections for rebates between

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manufacturers and Part D plans have a real potential to help reduce out-of-pocket costs for lung disease patients as long as sufficient protections for patients are included. However, the Lung Association is also concerned that removing the current safe harbor for supplemental rebates provided to Medicaid MCOs could increase costs and reduce patients' access to care in the Medicaid program and strongly urges the Administration to remove the proposed safe harbor changes for rebates to Medicaid MCOs from the final rule.

### Medicare Part D

Out-of-pocket costs for patients in the Medicare Part D program with serious and chronic health conditions, including lung disease, can be extremely burdensome and unaffordable. Especially if the plan has a coinsurance structure based on the list price of a medication, patients can be charged thousands of dollars for the medications they need to manage their conditions. For example, research from the Kaiser Family Foundation found that the median out-of-pocket costs for Part D enrollees for fourteen cancer medications all exceeded \$8,000 per year in 2019.<sup>3</sup> The proposed rule would change the prescription drug rebate system to eliminate the current protection for rebates provided to Medicare Part D plans and create a new safe harbor for rebates passed directly onto patients at the point of sale. This step could help to reduce out-of-pocket costs for lung disease patients enrolled in Medicare Part D.

The association between out-of-pocket costs and medication adherence is well-documented. Research has shown the high out-of-pocket costs are associated with patients' delaying care and failing to fill their prescriptions.<sup>4</sup> As a result, by helping to reduce out-of-pocket costs for patients in the Medicare Part D program, the proposed rule could in turn help to increase medication adherence among patients and ultimately improve health outcomes.

The proposed changes to the prescription drug rebate system are expected to increase premiums for beneficiaries; the proposed rule estimates an increase of between \$3.20 to \$5.64 per beneficiary per month for the 2020 plan year.<sup>5</sup> While the reduction in cost-sharing is expected to exceed the premium increase for certain patients, premium increases of this size could still create a burden for patients in the Medicare program, especially recognizing that the median annual income for Medicare beneficiaries is \$26,600.<sup>6</sup> The Lung Association urges CMS to closely monitor changes in premiums and cost-sharing for patients in each Medicare Part D plan to examine the impact of the proposed rule on patients, including those with lung disease, in the Medicare program.

As the proposed changes would significantly shift financial arrangements and incentives in the healthcare system, the Lung Association also urges CMS to closely monitor the impact of these changes on patients' access to care in the Medicare program. For example, CMS should engage in rigorous formulary review to ensure that any changes to the medications that plans cover or to the formulary management practices like prior authorization that plans use do not discriminate against patients with lung diseases or other high-cost health conditions. Additionally, CMS should use Medicare.gov, model notices and other communications with beneficiaries to explain these changes in the Medicare Part D program and their potential implications for patients' healthcare



costs. CMS must also ensure that the Medicare Plan Finder, scheduled to go live with information for the 2020 plan year on October 1, has timely, accurate and easy-to-understand information for patients to compare plans and their healthcare costs.

#### The Final Rule Should Not Apply to Medicaid

By removing the existing safe harbor for prescription drug rebates, the proposed rule would eliminate certain supplemental rebates received by Medicaid MCOs that help to lower federal and state prescription drug costs in the Medicaid program. The rationale for this policy is unclear; since Medicaid beneficiaries typically have low or no copays for their prescription medications, the current rebates could not be converted into point-of-sale rebates as they could under Medicare Part D.

The Administration's own analysis of the proposed rule predicts that 85 percent of additional Medicaid MCO rebates would no longer be negotiated, and only half of the rebates retained would shift into new rebates allowed under the proposed rule.<sup>7</sup> Overall, the Office of the Actuary (OACT) predicts that the proposed changes would cost the Medicaid program \$1.9 billion over the next ten years.<sup>8</sup> Furthermore, these costs to the Medicaid program could be even higher if list prices do not decrease as predicted in OACT's analysis. The Lung Association is therefore concerned about the impact of the proposed rule on the Medicaid program, a concern that has been shared by other stakeholders, including the nonpartisan Medicaid and CHIP Payment and Access Commission (MACPAC).<sup>9</sup>

If prescription drug costs in state Medicaid programs rise, Medicaid programs and Medicaid MCOs will likely respond by cutting benefits or using tools like prior authorization and step therapy to limit access to needed medications. These changes would harm access to care for lung disease patients. For example, restrictions like prior authorization can lead to delays in patients' access to necessary care and lead some patients to abandon treatment for their condition.<sup>10</sup> Additionally, 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.<sup>11</sup> Additional restrictions like step therapy could impede access to guidelines-based care. The Lung Association therefore urges HHS to retain the existing safe harbor for rates negotiated by Medicaid MCOs in the final rule.

#### Conclusion

The Lung Association believes the Administration's proposed changes to the safe harbor protections for rebates between manufacturers and Part D plans have a real potential to help reduce out-of-pocket costs for lung disease patients as long as sufficient protections for patients are included, but strongly urges the Administration to remove the proposed safe harbor changes for rebates to Medicaid MCOs from the final rule. Thank you for the opportunity to provide comments.



Sincerely,



Harold P. Wimmer  
National President and CEO

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<sup>1</sup> 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

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

<sup>3</sup> Cubanski J, Koma W, & Neuman T. The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019. Kaiser Family Foundation. Feb 1, 2019. Accessed at: <https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-findings/>

<sup>4</sup> 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

<sup>5</sup> Department of Health and Human Services, Office of Inspector General. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (OIG-0936-P). Feb 6, 2019. Accessed at: <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

<sup>6</sup> Kaiser Family Foundation. An Overview of Medicare. Feb 13, 2019. Accessed at: <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/>,

<sup>7</sup> Center for Medicare and Medicaid Services, Office of the Actuary. Proposed Safe Harbor Regulation. Aug 30, 2018. Accessed at: <https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0004&contentType=pdf>.

<sup>8</sup> Center for Medicare and Medicaid Services, Office of the Actuary. Proposed Safe Harbor Regulation. Aug 30, 2018. Accessed at: <https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0004&contentType=pdf>.

<sup>9</sup> Inside Health Policy, MACPAC Members Suggest Taking Medicaid Out of HHS Rebate Ban. March 8, 2019. Retrieved from: <https://insidehealthpolicy.com/daily-news/macpac-members-suggest-taking-medicare-out-hhs-rebate-ban?destination=node/108615>.

<sup>10</sup> 2017 prior authorization physician survey. *American Medical Association*, 2018 Feb. Accessed at: <https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf>.

<sup>11</sup> Baughman RP, Meyer KC, Nathanson I, et al. Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. 2012;142(5):e11S-e111S.

