May 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Rule: Medicare Program: Part B Drug Payment Model (CMS-1670-P)

Dear Acting Administrator Slavitt:

The American Lung Association appreciates the opportunity to submit comments with regard to the Centers for Medicare & Medicaid Services (CMS) proposed Medicare Part B drug payment model.

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The organization represents lung disease patients, their families, loved ones and caregivers.

The Lung Association acknowledges that Medicare is a major payer for lung cancer treatments. Lung cancer accounts for about one in six new cancer cases among the elderly, and in 2011, lung and bronchus cancer accounted for 13 percent of Medicare cancer expenditures.[1] Lung cancer also leads among all cancer deaths for those over age 65, accounting for 29 percent of all cancer deaths over age 65.[2]

Part B drugs included under the proposed model treat patients impacted by lung disease. The proposed includes intravenously administered drugs used to treat cancer; injectable drugs used in connection with the treatment of cancer; inhalation drugs administered through a nebulizer; and, certain oral anti-cancer drugs (Section II(A)(1) of the proposed rule).

The American Lung Association is deeply concerned and troubled by the proposed rule, as it will have grave negative impacts on access to care, patient costs and, ultimately, health outcomes. The Lung Association strongly urges CMS to address these concerns, including adding safeguards to protect Medicare recipients' access to quality care and exposure to high out-of-pocket costs. Absent modifications to the proposal that protect our nation's seniors, the Lung Association asks that CMS reconsider this proposal.

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Patient Costs

Out-of-pocket costs are a significant barrier to effective treatment for all disease patients, including those with lung disease. The proposed rule would not change the overall cost sharing amount paid by all enrollees, by creating a budget neutral alternative average sales price add-on revision amount (Section IX(D)(c)). However, the model proposed in the rule specifically states that money will be shifted away from hospitals and specialties that use high cost drugs (Section I(C)). If money is shifted away from some hospitals and specialties with the aim of keeping aggregate out-of-pocket costs the same, some patients will pay more for the care they need. The American Lung Association is concerned because the proposed model does not address which subpopulation of Medicare beneficiaries will have increased cost sharing through out-of-pocket expenses or premium costs based on specialty care, health condition and health care setting.

Any increase in cost sharing is a barrier to accessing health services. The Lung Association is concerned the proposed rule may also expose beneficiaries to additional barriers to access health services, including additional travel, wait time and cost sharing that can prevent the continuity of coordinated, quality care. These barriers are exacerbated for Medicare beneficiaries with comorbid health conditions requiring treatment in various health care settings; especially considering this subpopulations' need for care from different specialties across geographic areas from which the proposed rule intends to modestly shift money away from.

Additional concerns regarding out-of-pocket costs arise because the proposed payment model, which attempts to prevent the over-and-under-prescribing of high cost and low cost drugs, has not be tested. There is no indication that the incentives for providers to prescribe low cost drugs will be realized in a real world setting. This raises significant concern that Medicare beneficiaries will be exposed to high out-of-pocket costs due to reliance on both low and high cost drugs to treat their health conditions.

An analysis by Avalere Health[3] indicates that out-of-pocket costs would increase for Medicare beneficiaries when the drug's average sales price is less than $480 per day under the proposed payment model. When the average sales price is more than $480 per drug per day, the provider's reimbursement and the patient's out-of-pocket costs would both decrease. However, the American Lung Association's concern is that in the latter circumstance, patients may be referred to different geographic locations or a higher cost health care setting which would receive a higher reimbursement under the proposed model. The Lung Association is concerned that this may expose patients to increased cost sharing and in turn decrease access to care.

The adverse implications of the proposed payment model is significant when Avalere's analysis indicates that seven of the 10 drugs which will have the largest reduction in reimbursement are cancer drugs and more than 1 million Medicare beneficiaries were treated with one of these 10 drugs in 2014. The Lung Association is also concerned about the adverse implications the proposed payment model may have on lung disease patients. The U.S. Food and Drug

Administration has recently approved new drugs for the treatment of patients with metastatic non-small cell lung cancer (NSCLC)—with one new drug approved in 2016 and six new drugs in 2015.[4] These drugs, while potentially expensive, will extend the lives of those living with lung cancer, if patients have access to them.

Due to the concerns that the proposed model would increase cost sharing for Medicare beneficiaries, the American Lung Association requests CMS to conduct a full analysis of the impact on patient out-of-pocket costs prior to implementing the proposed model.

Access to Care

CMS's proposal states the payment model takes into account observed and unobserved differences between the intervention and control groups of the payment model. This attempts to ensure that any measurable impact will be due to the intervention itself. However, integrating the changing provider networks and their adequacy is essential; the geographic selection process of the proposed payment model relies on the service location ZIP code for physician drug claims. The nature and degree to which the positive health outcome from the proposed payment model can be adequately measured and sustained in light of shifting provider networks should be addressed to ensure patient's access to continuous and coordinated, quality care. In fact, CMS decided to use the proposed model's geographic selection process despite CMS's acknowledgment of the possibility for large practices being simultaneously subject to different payment methods because they may have practice locations in more than one primary care service area. This circumstance may have the provider encourage patients to receive a drug in a location within the control arm of the model that provides a higher payment (ASP + 4.3 percent under sequestration) than the intervention arm (ASP + 0.86 percent under sequestration + flat fee under sequestration) (Section II(C)(1)).

The gap in the overall range of percentage change estimated for Medicare Part B payments for specialties in general, as well as specialties in urban areas and in rural areas specifically, are -3.3 to 50.2 percent, - 0.3 to 50.2 percent and -3.2 to 82.1 percent, respectively (Table 2 in proposed rule). The American Lung Association is concerned that this gap may disproportionately affect Medicare beneficiaries through increased cost sharing as well as limited geographic access. Further barriers to quality care appear when beneficiaries seek access to health services for their health conditions across the continuum of care from which the proposed model intends to modestly shift money away from some health settings and specialties of care.

Avalere Health's analysis indicates that some specialists, including oncologists, will experience the reduced reimbursement rate with no available lower-cost drug alternatives. Oncologists are projected to account for approximately 14 percent of the reduced reimbursements under the proposed payment model. When the drug's average sales price costs more than $480, the provider's reimbursement decreases and the patient's out-of-pocket costs decreases. The American Lung Association's concern is that the provider may refer the patient to a different location which has the higher reimbursement formula, thereby hindering the patient's timely and geographic access to care.

The American Lung Association is concerned that these changes to the payment structure will negatively impact patients because it may disrupt the continuity and coordination for equitable access to affordable and quality care. The potentially adverse impact on patients may lead to further challenges of addressing the dynamic health care needs of patient populations across various geographic areas under this proposed model.

Quality Health Measures

The proposed model discusses the application of value-based payment tools with the aim of incentivizing high value drugs for patient care. The value-based payment tools would be implemented in Phase II of the proposed model toward both control groups of average sales price + 6 percent and average sales price + 2.5 percent + $16.80 flat fee as follows: average sales price + 6 percent + value-based payment; and, average sales price + 2.5 percent + $16.80 flat fee + value-based payment [under sequestration: 6 percent is approximately 4.3 percent; 2.5 percent is approximately 0.86 percent; and, $16.80 is approximately $16.46).

The Lung Association has concerns with regard to all the value-based payment tools as well as specific concerns with certain value-based payment tools.

General Concerns with proposed Value-Based Payment tools

The general concerns with all of the proposed value-based payment tools are:

1. There are no quality measures established to monitor and evaluate patient health outcomes associated with the administration of the drugs under this proposed model.

2. Clinical effectiveness varies by the patient's unique medical characteristics, health condition(s) and treatment(s). The patient's care may be at risk if the determination of 'high value' leads to incentivizing providers to administer drugs which may not necessarily improve the patient's health outcomes.

3. Metrics have not been established to address patient health outcomes. Any metrics established need to take patients with comorbid health conditions into account.

4. CMS is considering comments for potential standardization of metrics under their value-based payment models. Standardization of metrics must take into account variations with tailored, personalized medicine for health conditions as well as for comorbid health conditions.

Reference Pricing

CMS' stated aim with reference pricing described in Section III(B)(1) of the proposed rule is to set a standard payment or benchmark rate that will be the average price for a group of therapeutically similar drugs within an Healthcare Common Procedure Coding System (HCPCS) code. Clinical effectiveness will be used to determine a benchmark rate. The payment for the most clinically effective drug will be the benchmark rate and others are adjusted downward. While CMS'

objective with reference pricing is to incentivize providers to not administer higher cost drugs, there is no guarantee this will improve patient health outcomes.

The clinical effectiveness in administering the same or similar drugs within a similar class of drugs to patients may vary between patients, based on the patient's unique biology and the stage of the health condition, among other factors. Patients' health outcomes may be at risk if a provider is discouraged to administer a higher cost drug. Potential negative impacts of switching to a lower cost drug include changing a course of treatment that is currently working to improve the patient's symptoms and switching from a drug that has shown to be more effective for a specific stage during disease progression.

The reference pricing approach establishes that balance billing will not be implemented with an example of a higher cost drug, within a therapeutically similar class of drugs, which has its repayment adjusted downward to the weighted average or benchmark rate determined within that HCPCS code. However, the proposed model's aim is to both reduce the prescription of high cost drugs, and encourage prescribing of low-cost drugs in light of the add-on revision amount and flat fee. If providers are incentivized to prescribe lower cost drugs, which are not personalized to the individual patients and their health conditions, but whose reimbursement may have an upward adjustment toward the benchmark rate established for that therapeutically similar class, positive patient outcomes are put in jeopardy.

The American Lung Association is concerned that these changes to the reference pricing will negatively impact patients because the generalization of clinical effectiveness to determine a benchmark or standard rate of reimbursement within a therapeutically similar class of drugs ignores personalized treatments that should continue to be administered for the patient's best interest to gain better health outcomes.

Indication Pricing

Indication pricing described in Section III(B)(1) of the proposed rule is to establish varying prices for the same drug that is used to treat different conditions or indications, based on clinical effectiveness. Indication pricing leads to lower payment for the drug when it results in less effective treatment and higher payment for the drug when it has a significantly better result. As discussed above, clinical effectiveness varies by the patient's unique medical characteristics, health conditions and treatments. Indication pricing does not factor these into the new payment scheme.

The American Lung Association is concerned that indication pricing will negatively impact patients because clinical effectiveness may vary among patients both within a particular health condition and between different health conditions that the drug treats. If the assessment for clinical effectiveness to evaluate indication pricing is not tailored to personalized treatments, the reimbursement model disincentivizes the administration of treatments that are patient-centered and lead to sub-optimal health outcomes.

Health Outcome Pricing
CMS' stated aim with health outcomes pricing, described in Section III(B)(1), is to allow CMS to enter into voluntary agreements with manufacturers to link health care outcomes to payment. Payers and pharmaceutical manufacturers will be encouraged to contract in outcomes-based risk-sharing agreements to link payment for drugs to patient health outcomes.

The challenges associated with risk-sharing agreements include the lack of acceptable outcome metrics and the difficulties with determining the effect of treatments.[5] The American Lung Association is concerned that health outcome pricing will negatively impact patients for the following reasons:

1. Health outcome pricing may lead to selective health outcomes that are incentivized to treat based on payments linked to those health outcomes. This could marginalize subgroups of patient populations whose health condition outcomes may not be linked to the incentivized payments.

2. The proposed model does not account for the evaluation of patient health outcomes under circumstances that may involve:

    a. A combination of drugs to treat a health condition
    b. A combination of drugs to treat comorbid health conditions
    c. Health conditions with varying stages of diagnosis
    d. Health conditions with varying stages of treatments, including treatments which may require a combination of drugs

3. And, since these agreements are voluntary, the proposed model does not necessarily provide safeguards to ensure equitable access to quality care for Medicare beneficiaries if the voluntary agreements were terminated in various geographic areas.

The American Lung Association's concern with the value-based payment tools is that the generalization of clinical effectiveness and health outcomes tied to drug payment does not consider personalized care for the patient and will negatively impact the patient's quality of care.

Conclusion
The American Lung Association strongly encourages CMS to reconsider the proposed payment model because of the potential significant adverse impacts on all Medicare patients, including those living with lung disease. Any final rule needs to include patient safeguards to protect Medicare enrollees from high out-of-pocket costs and preserve access to quality care. The Lung Association asks that any new payment model take into account access to care, while keeping all drugs affordable. The American Lung Association requests that CMS address our concerns to resolve the potential negative impacts on patient cost sharing, access to care and quality health care.

The American Lung Association appreciates the opportunity to submit our comments for the proposed Part B payment model.

Sincerely,

Harold P. Wimmer
National President and CEO

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[1] American Cancer Society. *Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage. (2013)* http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf Accessed April 27, 2016.
[2] *Id.* citing, National Center for Health Statistics. Prepared by the Surveillance and Health Services Research Program of the American Cancer Society, 2012.
[3] Avalere Health, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers". http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s April 7, 2016
[4] U.S. Food and Drug Administration: Hematology/Oncology (Cancer) Approvals & Safety Notifications. http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm Accessed May 2, 2016.
[5] Neumann, P.J., Chambers, J.D., Simon, F., & Meckley, L.M. (2011) Risk-Sharing Arrangements That Link Payment For Drugs To Health Outcomes Are Proving Hard To Implement. *Health Affairs*, 30(12), 2329-2337.