November 20, 2017

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

Re: Centers for Medicare & Medicaid Services: Innovation Center New Direction

Dear Administrator Verma:

The American Lung Association appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Innovation Center's new direction.

As the leading organization working to save lives by improving lung health and preventing lung disease, the American Lung Association is the voice of the 32.2 million Americans living with lung disease.

The Lung Association is encouraged by CMS' efforts to engage stakeholders and patients, promote patient-centered care and improve quality while reducing costs. However, the Lung Association is concerned that value will only be defined by costs and exclude quality measures important to patients.

Patient-Centered Care

The American Lung Association recognizes that patient-centered care should reflect the needs of patients and variations in what they value in their care. Providing patients with information about care options empowers them to engage in shared decision making and make decisions around outcomes they value. Different patients desire different outcomes from their treatment courses. Asthma patients, for example, may value asthma control, utilization, adherence, pulmonary function, missed days of school or work, exacerbations, or others. Patients with lung cancer or COPD may value quality of life, extension of life, pulmonary function, symptom management, treatment complications or others in choosing their treatment.

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When patients share their desired outcome with their provider, their provider can work with them to make meaningful decisions over their care and personalize their treatment. The Lung Association is encouraged by CMS' direction towards greater price and quality transparency to engage patients and provide patients information to make choices about their care. However, the Lung Association is troubled with the phrase "ownership of their health" when used to refer to empowering beneficiaries with flexibility and information to make choices as they seek care. The phrase could potentially be used to penalize patients who may choose treatments with outcomes that matter to them, but may not align with the cost-driven value.

Although Section 1115A of the Affordable Care Act calls for evaluating payment models against a "patient-centeredness criteria," no criteria have been formally developed and released for public comment. The Lung Association hopes that CMS will pursue the creation of a criteria for patient-centeredness in Centers for Medicare and Medicaid Innovation (CMMI) models moving forward and allow for meaningful stakeholder engagement. Patients and organizations representing these patients must be given the opportunity through open comment periods or collaborations to provide meaningful input in the discussion of what constitutes value in healthcare and to ensure a patient-centered lens.

<u>Value</u>
High value healthcare is achieving the best care at the lowest possible cost, but value should also be defined by outcomes that matters to the patient. The Department of Health and Human Services' (HHS) created the Health Care Payment Learning and Action Network (LAN) to align stakeholders and accelerate the transition to value-based payment. One of the seven principles established was that "Patients must be empowered as partners in healthcare transformation; changing providers' financial incentives is not sufficient to achieve person-centered care." Value-based frameworks must align quality and value with outcomes.

The Lung Association is concerned that value-based payment may negatively impact patients if proper patient input is not considered for the following reasons:

a. Value-based reform that only evaluates cost as a singular indicator fails to recognize the variations of value for patients. As mentioned previously, patients value different outcomes from their courses of treatment.
b. If the variation in patient values are not incorporated into outcome quality measures, patients may value what is considered low-value treatments over high-value treatments due to the outcomes they desire and may potentially be penalized for their treatment decision.

The Lung Association strongly believes that it is critical that quality measures do not discriminate against patients with chronic disease, such as those living with lung disease. Chronic disease treatments have benefits over an extended period of time. Thus, cost savings alone will not accurately capture the entire value of the treatment if it does not account for this extended period of time. Similarly, chronic disease patients often use combinations of drugs to treat their condition or have comorbid health conditions. These factors must be accounted for when establishing the

value of treatments. Quality measures need to be risk-adjusted to ensure that it is applicable to the patient and the patient's health condition. It is also important that treatment breakthroughs that are high-cost but high-value are still encouraged. For patients with lung disease, these treatments represent a new lease on life that cannot be quantified by cost alone.

Preventive care should also be factored into value considerations. Preventive services can avert downstream costs and result in cost savings years later. For example, every dollar spent in the Massachusetts Medicaid Tobacco Cessation Program resulted in an average savings of $3.12 in healthcare expenditures and a $2.12 return on investment that was realized an average of 1.3 years after receiving cessation treatment.[1] Payment models must support these early interventions that can blunt the onset of chronic disease. Proactively incorporating these preventive services into the determination of value for treatments will result in better patient outcomes and less costly exacerbations down the line.

Thus, quality measures must be carefully developed to ensure that outcomes that matter to patients are recognized and factors that impact outcomes are acknowledged in determining value. The Lung Association recognizes CMS' efforts to design, test and implement programs in a way that drives towards better value for patients. Patients and other stakeholders must be provided sufficient opportunity to comment to ensure that patient needs are reflected in value determinations.

Alternative Payment Models

The Lung Association appreciates CMS' commitment to greater transparency in innovative model design and evaluation. Alternative payment models such as Accountable Care Organizations (ACO) and bundled payments are promising for coordinating care between providers to address conditions like asthma and tobacco cessation services. For many health conditions, cross-sector integration can align and improve patient health outcomes. Asthma control relies on regular adherence to pharmacotherapy, active engagement with self-management behaviors and controlling environmental triggers. MassHealth (Massachusetts Medicaid) utilized different payment initiatives for asthma, including Patient-Centered Medical Homes (PCMH), bundled payments for children with high-risk asthma and capitated payments based on quality and shared savings.[2] These alternate payment models provide clinicians the flexibility to offer high value services traditionally considered social or public health services to better coordinate care.

Similarly, treatment for smoking cessation is not a one-size-fits-all. Tobacco users often require a combination of pharmacotherapy and counseling to help them quit smoking and patients often try more than one treatment before finding the right one. Bundling payments for tobacco cessation can help coordinate different treatment combinations to help smokers successfully quit. Allowing

[1] Richard P, West K, Ku L (2012) "The Return on Investment of a Medicaid Tobacco Cessation Program in Massachusetts." PLoS ONE 7(1): e29665. doi:10.1371/journal.pone.0029665

[2] Farmer SA, Patel K, George M, McStay F, Hart R, McClellan M (2015). A Case Study in Payment Reform to Support Optimal Pediatric Asthma Care. Accessed at: https://www.brookings.edu/wp-content/uploads/2016/06/Asthma-Case-Study.pdf

stakeholders to comment and collaborate in the design of these models will ensure that patient needs are accurately reflected and holistic management treatments are utilized.

Payment models should also recognize guidelines-based care to ensure that current best evidence is used in making decisions about the care of individual patients. Guidelines-based care provides the best value by improving outcomes at a reasonable cost. If a treatment protocol is the recommended standard, any coverage and payment model should utilize the protocol into its framework such that evidence, patient values and patient outcomes are aligned in the decision-making process.

The Lung Association is concerned that alternative payment models provide too great of a risk for providers who are not ready to take on the downside risks of value-based payment, which may result in providers leaving the Medicaid network. This will negatively impact Medicaid patients and will restrict patient choice. It is also important to note that voluntary participation in models may not provide representative results. Early adopters of new voluntary payment models are likely plans and facilities that know they will benefit from participation. Closer evaluation is needed to ensure that challenges to implementing these models more broadly is addressed and that patients will not lose access to care. Thus, the Lung Association encourages CMS to prepare providers for changes in payment and consider concerns outlined in the value section above (ensuring that the health conditions of patients and their values are reflected) in any innovative models.

The Lung Association acknowledges that innovative models and waivers can offer new approaches to delivering care that benefits patients. However, any models or waiver approvals must ensure that healthcare is affordable, accessible and adequate to align with our Consensus Healthcare Reform Principles (attached). Any proposed market-driven reforms must include patient protections to ensure patients have access to the treatments they need and that care is affordable. The Lung Association encourages CMS to work with states applying for Medicaid waivers to develop proposals that focus on patients and improve health outcomes without reducing access and affordability.

Thank you for reviewing our comments. The American Lung Association appreciates the opportunity to comment on CMS' new direction for CMMI.

Sincerely,

Harold P. Wimmer
National President and CEO

Consensus Healthcare Reform Principles

Today, millions of individuals, including many with preexisting health conditions, can obtain affordable health care coverage. Any changes to current law should preserve coverage for these individuals, extend coverage to those who remain uninsured, and lower costs and improve quality for all.

In addition, any reform measure must support a health care system that provides affordable, accessible and adequate health care coverage and preserves the coverage provided to millions through Medicare and Medicaid. The basic elements of meaningful coverage are described below.

Health Insurance Must be Affordable – Affordable plans ensure patients are able to access needed care in a timely manner from an experienced provider without undue financial burden. Affordable coverage includes reasonable premiums and cost sharing (such as deductibles, copays and coinsurance) and limits on out-of-pocket expenses. Adequate financial assistance must be available for low-income Americans and individuals with preexisting conditions should not be subject to increased premium costs based on their disease or health status.

Health Insurance Must be Accessible – All people, regardless of employment status or geographic location, should be able to gain coverage without waiting periods through adequate open and special enrollment periods. Patient protections in current law should be retained, including prohibitions on preexisting condition exclusions, annual and lifetime limits, insurance policy rescissions, gender pricing and excessive premiums for older adults. Children should be allowed to remain on their parents' health plans until age 26 and coverage through Medicare and Medicaid should not be jeopardized through excessive cost-shifting, funding cuts, or per capita caps or block granting.

Health Insurance Must be Adequate and Understandable – All plans should be required to cover a full range of needed health benefits with a comprehensive and stable network of providers and plan features. Guaranteed access to and prioritization of preventive services without cost-sharing should be preserved. Information regarding costs and coverage must be available, transparent, and understandable to the consumer prior to purchasing the plan.