

July 6, 2021

The Honorable Shalanda Young Acting Director Office of Management and Budget 725 17th Street, NW Washington, DC 20503

# Re: Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government

**Dear Acting Director Young:** 

Thank you for the opportunity to comment on the Office of Management and Budget's (OMB) Request for Information (RFI) entitled, "Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government."

The American Lung Association is the oldest voluntary public health association in the United States, representing the millions of individuals with or at risk of lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Supporting investments and policies that eliminate health disparities caused by systemic racism and building health equity across all policy areas are core priorities in the Lung Association's Public Policy Agenda.<sup>1</sup> All individuals should have a fair and just opportunity to be as healthy as possible, regardless of race or ethnicity, sex, gender identification, religion, national origin, age, income, sexual orientation or disability. The Lung Association applauds the Administration's recent executive orders on advancing equity and the RFI's broad reach across all government agencies, programs and funding.

The Lung Association offers the following comments on equity assessments and strategies, barrier and burden reduction, and stakeholder and community engagement. While we recognize the important role that education, criminal justice and other federal programs and policies have on health equity, our comments will focus on our work on lung health, access to care, climate change and healthy air, and tobacco control.

### **Equity Assessments and Strategies**

Data are crucial for identifying disparities and where policy interventions are needed to address inequities. Data should be consistent across federal agencies and programs, to the extent possible, and reflect the full range of demographic characteristics of populations that have been marginalized.

#### Collect Data to Advance Equitable Tobacco Control Policies

To advance health equity related to tobacco use, dependency and secondhand smoke and tobacco product emissions, it is important to establish consistent national tracking and

monitoring systems focused on health equity metrics for populations disproportionately impacted by tobacco.<sup>2</sup> This will help identify areas of concern and drive the development of interventions that address social determinants of health.

Research on tobacco cessation needs to reflect the current demographics of active smokers. The EAGLES trial had the largest inclusion of racial and ethnic minority smokers, but it was still less than 30%.<sup>3</sup> Typically, less than 15% of study participants are from racial and ethnic minority groups in tobacco cessation treatment clinical trials. Future research needs to include all demographics that smoke to truly discover what treatment helps everyone quit. This is also the case for research aimed at promoting cessation among youth.

Further advancement in health equity will also occur with research on the connection between tobacco and opioid misuse, building on some small studies showing such a connection.<sup>4</sup> To better be able to design inclusive programs to help patients quit and identify individuals at risk of becoming addicted to tobacco and abuse opioids, it is vital to understand the connection between these two substances on a broader level.

The credibility and quality of the data provided by the Centers for Disease Control and Prevention (CDC) are crucial to the work being done nationwide on tobacco prevention and control. The Lung Association urges CDC to continue the collection of national and state-by-state data on tobacco use and secondhand smoke exposure, irrespective of these data not being included in Healthy People 2030. Particularly important for addressing health equity and tobacco use disparities will be CDC continuing to collect data, annually to the maximum extent possible, on the populations that use tobacco products at the highest rates, including racial and ethnic minorities, persons with lower-income and lower education, individuals who identify as Lesbian, Gay, and Bisexual (LGB) and those with behavioral health conditions.<sup>5</sup> Current national data on use of tobacco products by transgender individuals and sub-populations of Hispanic and Asian-American adults are urgently needed as well.

In addition to CDC, the Centers for Medicare and Medicaid Services (CMS) also plays a key role in promoting the collection of key data related to tobacco cessation. CMS recently proposed removing Joint Commission measure TOB-2/2a from reporting requirements in the FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates. TOB-2/2a is Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention, and the logic for its removal is that brief tobacco use interventions are being provided or offered nearly ubiquitously. As a result, CMS asserts that this measure is not needed to change provider behavior and creates unnecessary paperwork, points with which the Lung Association fundamentally disagrees.<sup>6</sup> Indeed, the data show providers are not providing or offering tobacco cessation interventions for the behavioral health population; only 37.6% of behavioral health treatment facilities and 47.4% of substance abuse treatment facilities offered tobacco cessation counseling to their patients, and approximately only a quarter of these facilities provided cessation medications.<sup>7</sup> Providers advising patients to quit is an important intervention that can help save lives. Additionally, maintaining and restoring TOB-1 (Tobacco Use Screening) will help ensure CMS has the data necessary to work to reduce health disparities in tobacco use among the behavioral health population.

The Tobacco Use Supplement to the Current Population Survey is a National Cancer Institute (NCI)-sponsored survey of tobacco use that has been administered as part of the U.S. Census Bureau's Current Population Survey approximately every 3-4 years since the early 1990s.<sup>8</sup> It collects data on a variety of topics that are critical to addressing tobacco-related health disparities including smoking history, quit attempts and intention to quit, use of menthol cigarettes, workplace and home smoking restrictions, and attitudes towards smokefree policies in public places. It is the primary source of data to help understand the extent of secondhand smoke exposure in the U.S., which causes over 41,000 deaths in the U.S. each year.<sup>9</sup> Conducting the survey on a more frequent basis would make these data even more reliable and relevant.

Finally, the American Lung Association urges the Food and Drug Administration (FDA) to use the real-time data coming from FDA's Population Assessment of Tobacco and Health (PATH) Study to determine who is using a variety of tobacco products, including e-cigarettes, to assist with the Premarket Tobacco Product Application (PMTA) process. The PATH Study is a national longitudinal study of tobacco use and how it affects the health of people in the U.S. It looks at reasons why people use or do not use tobacco, how people quit using tobacco and changes in people's attitudes toward tobacco over time. It also looks at differences in tobacco-use related attitudes, behaviors and health among men and women, people of different races and ethnic groups and people of different ages. Using the findings from the PATH Study while reviewing the applications submitted by tobacco companies can help FDA make decisions that promote health equity and reduce disparities.

### Improve the Quality and Consistency of Data on the Burden of Asthma

Research shows that while the number of people living with asthma has increased, people with asthma are better managing their disease. However, the gains have not been universal. Asthma prevalence rates are disproportionately high in racial and ethnic minority groups, especially among Black individuals and American Indians and Alaska Natives. Non-Hispanic Black individuals are nearly three times more likely to die from asthma than white individuals. Additionally, children with Medicaid coverage are more likely to receive care in the emergency department and be hospitalized as a result of their asthma than their peers with other health coverage.

The CDC's National Asthma Control Program (NACP) tracks asthma prevalence, promotes asthma control and prevention and builds capacity in state asthma programs. Regularly collected, comprehensive data that can be compared across all 50 states and include asthma prevalence and key measures of asthma control (such as symptoms, medication use, self-management education and environmental factors) for both adults and children are critical to the work of the American Lung Association and many other stakeholders working to help patients with asthma. Yet current funding for the NACP does not enable the program to support all 50 states, contributing to gaps in data collection. Additional support and funding for the NACP is needed to provide better surveillance, and therefore better management and treatment, of asthma.

#### Improve the Collection of Data on Disparities within Chronic Disease

Chronic diseases represent seven of the 10 leading causes of death and account for 90% of the nation's \$3.8 trillion in annual health care costs. One of those seven diseases is chronic obstructive pulmonary disease (COPD). Recognizing the devastating impact of COPD, federal agencies, at the request of Congress, created the National COPD Action Plan. In addition to the many critical activities called for in this plan, federal agencies identified the need to "collect detailed information about population-specific health disparities in COPD prevention, diagnosis, care, and treatment." With better data on health disparities, federal agencies and other COPD stakeholders can better tailor policy and public health interventions to meet the needs of the community and ultimately save lives. Interventions informed by data can have a significant impact on chronic disease as chronic diseases often can be prevented and/or managed through such interventions (e.g., tobacco prevention and cessation).

Despite the recognition of the importance of additional data collection, however, the National COPD Action Plan has yet to be carried out in full. In order to further the progress of the National COPD Action Plan, improve data collection and address the burden of chronic disease in the United States, programs at CDC need robust and sustained funding. In our view, the current funding for the Centers for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) falls far short of what is needed to prevent chronic disease, slow its spread and protect vulnerable populations. The work being done at NCCDPHP is rooted in addressing social determinants of health to reduce barriers and promote health equity. Increasing NCCDPHP's budget will support efforts to prevent chronic diseases, improve health outcomes, address health disparities and ultimately improve underlying health and wellness for all.

Improve Data to Inform Healthcare Programs and Policies, Particularly in Medicaid Within CMS, the agency should first evaluate data currently collected and the process for collection. Where it is not already being done and where it is possible, state and federal entities should strive to collect self-reported data on race, ethnicity, gender, disability and sexual orientation. When collecting these data though, it should be made clear why data are being collected and how the data will be used. Individuals collecting this information should undergo cultural competency and skilled communication training to regain trust and minimize the trauma and stigma that underserved communities may experience when interacting with government entities.

CMS collects and posts Medicaid enrollment data from each state on a monthly basis and, after cleaning the data, posts it on Medicaid.gov. <sup>16</sup> Currently, these monthly reports break down enrollment by state and by adult/child. CMS should further stratify adults and children enrolled in each state's Medicaid program by race/ethnicity, as well as gender, sexual orientation, disability status and preferred language where possible.

Additionally, CMS operates the Transformed Medicaid Statistical Information System (T-MSIS).<sup>17</sup> This data set contains demographic information about Medicaid beneficiaries, as well as data on their use of services in both fee-for-service and managed care delivery systems. These data are essential to assessing the equity of beneficiary access to care. Currently, the

completeness of the demographic information reported by states, including data on race/ethnicity, is one of a number of quality issues that CMS has identified. Understandably, CMS is not planning to initiate state compliance actions during or immediately following the COVID-19 public health emergency (PHE). However, CMS should issue guidance to states emphasizing the importance of reporting timely, complete and accurate race/ethnicity data to T-MSIS and outlining the compliance actions it will take, if necessary, to ensure such reporting upon the expiration of the PHE.

#### Strengthen and Expand Air Quality Monitoring

The American Lung Association supports the strengthening and expansion of the nation's network of air pollution monitors in the United States and urges greater attention and resources devoted to the air quality monitoring system to ensure that accurate and reliable information about the quality of the air is available for all parts of the country, particularly currently and historically underserved communities. The placement of air quality monitors (e.g., the location and type of monitors) must take equity considerations into account, including capturing local air pollution hot spots, and collect more complete data at the local level. Equity considerations also call for attention to qualitative or technology-based interim processes and procedures for capturing information about air quality emissions where there is inadequate or incomplete monitoring and for the timely dissemination of information to affected communities.

Although this information would not fully substitute for information provided by monitors, or meet certain statutory requirements for Environmental Protection Agency (EPA), it would provide an important base of information as agencies evaluate the potential environmental justice implications of policies. Reliable air quality information is critical for federal agencies to be in a position to develop specific strategies to reduce air pollution – on its own or in partnership with state and local governments – and protect the health of all communities.

#### **Barriers and Burden Reduction**

Lack of data should not be an excuse for slowing work on equity and those who resist pursuing health equity cannot be allowed to undermine robust data collection. It is well known that barriers and burdens for underserved populations exist in almost all federal programs. The Lung Association offers the following comments on areas where federal agencies can prioritize rulemaking and take other prompt action to reduce barriers that make it harder for groups that have been marginalized to live healthy lives.

# Encourage Swift FDA Action to End the Sale of Menthol Cigarettes and Flavored Cigars to Reduce Tobacco-Related Health Disparities

Ending the sale of menthol cigarettes and flavored cigars will reduce health disparities, prevent young people from beginning a tobacco addiction and encourage tobacco users to quit. While the number of people smoking continues to decrease, the presence of menthol on the market continues to be a major public health issue. As of 2018, about 38% of all cigarette sales were menthol cigarettes, the highest rate since major tobacco companies were required to report this data. Scientific evidence indicates that menthol smokers are less likely than non-menthol smokers to successfully quit smoking despite having a higher urge to end their tobacco dependence.<sup>18</sup>

For generations, the tobacco industry has intentionally targeted Black, Brown and other marginalized communities with the marketing of menthol cigarettes, resulting in disparate levels of death and disease caused by tobacco use. In fact, 85% of Black smokers, 48% of Hispanic smokers and 41% of Asian smokers use menthol cigarettes compared to 30% of white smokers. Other vulnerable groups of individuals impacted by the tobacco industry's targeted marketing include the Lesbian, Gay, Bisexual, Transgender, Queer and/or Questioning, Intersex, and Asexual (LGBTQIA+) community and young people. Data show that menthol cigarette use is more prevalent among the LGB community at 49% compared to 40% among heterosexual individuals.

The tobacco industry has not only intentionally targeted communities that have been marginalized with menthol cigarettes, but they have also done the same with flavored cigars. The tobacco industry is also disproportionately advertising and selling little cigars and cigarillos (LCCs) at lower prices in stores located in neighborhoods disproportionately composed of racial and ethnic minority individuals and individuals with low incomes.<sup>20</sup> Tobacco retailers in neighborhoods consisting of predominantly Black individuals are more saturated with LCCs, which undermines cessation and raises concerns about susceptibility to LCC use and dual use of LCC and cigarettes.<sup>21</sup>

Removing menthol cigarettes and flavored cigars from the marketplace would be the most significant action taken by the FDA since it began its oversight of tobacco products in 2009. The Lung Association is encouraged by the news of FDA planning to propose these two rules and we urge swift FDA action. It is critical for FDA to remove all menthol cigars and cigarillos at the same time it removes menthol cigarettes. The FDA must recognize that the tobacco industry will discourage people from quitting and instead urge menthol users to switch to other menthol products. It is also imperative that FDA not authorize any menthol flavored e-cigarettes or other flavored tobacco products through the premarket tobacco review process. With 480,000 lives continuing to be lost to tobacco each year, the Lung Association reiterates that the removal of menthol cigarettes and flavored cigars from the marketplace will help to end health disparities associated with tobacco use.

In the 2019 National Youth Tobacco Survey, e-cigarettes were the most commonly used tobacco product among Black high school students at 17.7% and use of cigars and cigarillos among Black youth remains high at 12.3%. Use of cigars among high school students overall is 7.6%. Black young adults are 50% more likely to smoke cigars in the past 30 days<sup>22</sup> and three times more likely to smoke flavored cigars compared to their white counterparts.<sup>23</sup> These key findings all point to the need to prohibit the sale of all flavored tobacco products, including e-cigarettes, cigars and cigarillos, to effectively reduce tobacco use disparities.

#### Promptly Finalize New Rule on Healthcare Discrimination

The Administration must issue new implementing regulations for Section 1557 of the Affordable Care Act (ACA), which established an expansive prohibition on discrimination on the basis of race, color, national origin, sex, age or disability by any health program or activity that receives federal funding. The Lung Association applauds the Administration's recent notice that it will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex as barring

discrimination on the basis of sexual orientation and gender identity.<sup>24</sup> But far more steps are needed to stamp out discrimination in healthcare and to reduce burdens to care persistently faced by many.

A new rule should codify Section 1557's applicability to discrimination on the basis of gender identity and sexual orientation as well as revisit many of the other protections erroneously stripped from the books by the prior Administration's rulemaking in this area. First, the rule must recognize the broad reach of the statute to a range of healthcare programs and activities previously covered under the 2016 rule but inexplicably excused from compliance by the prior Administration. Such a rule should also reinstate protections against discriminatory benefit designs, reinstate notice and language access requirements, strengthen protections for people with limited English proficiency (LEP) and ensure the government and private individuals have sufficient tools to address violations of Section 1557, including through a private right of action.

#### Reduce Barriers to Enrollment in Medicaid

Medicaid expansion has been a lifeline to millions of patients and consumers across the country, especially in the midst of the COVID-19 pandemic. Unfortunately, many state Medicaid programs have policies and procedures in place that create administrative burdens on patients that lead them to erroneously lose their coverage. For example, unstable housing, which was exacerbated during the pandemic among low-income enrollees, may result in lost or misplaced mail, yet many states send a single notice/request for information that patients must respond to in order to maintain their coverage. And in many states, Medicaid eligibility also determines eligibility for other public benefits, risking additional hardship for underserved communities. CMS should work with states to evaluate their enrollment and renewal procedures to ensure eligible individuals are not excluded from the program and prioritize erroneous denials and terminations of coverage in the agency's oversight efforts.

The end of the federal COVID-19 PHE will also be a critical period to ensure that people receiving coverage through the Medicaid program do not erroneously lose access to care. CMS needs to update previous guidance, or issue new guidance, on the unwinding of the PHE that protects people of color and other underserved populations against erroneous terminations of coverage. In such guidance, CMS should provide a full year for state Medicaid agencies to fully return to normal eligibility and enrollment operations following the end of the PHE. This will ensure that state systems, call centers and eligibility workers are not overwhelmed and that underserved populations are more likely to get the necessary assistance to stay enrolled in coverage. States should be notified that CMS will consider racially disparate outcomes as it monitors state resumption of normal eligibility and enrollment requirements. Additionally, CMS should also require states to review eligibility for all individuals prior to disenrollment or minimally shorten the look-back period from six to three months. Conducting a fresh review of eligibility will help protect eligible individuals, especially those in underserved populations, from a gap in, or worse, a loss of coverage while reducing the administrative inefficiency and costs associated with churn.

Additionally, CMS should promptly take action to help states implement expansions of coverage for groups that have been historically marginalized. For example, CMS should release guidance

required under the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act regarding Section 1115 demonstration requests to facilitate Medicaid enrollment and provide healthcare services to individuals within 30 days of release from incarceration. CMS should also issue guidance on the implementation of the state plan option to extend postpartum coverage that was passed through the American Rescue Plan Act, to include clarification on the eligibility categories that can receive extended coverage. In this guidance, CMS should also highlight pathways by which Medicaid and/or CHIP could provide extended postpartum coverage to otherwise ineligible pregnant and postpartum individuals outside traditional eligibility pathways (i.e., through a Section 1115 demonstration, a CHIP Health Services Initiative, or other options).

## Increase Support for Communities to Enroll in and Utilize Quality, Affordable Healthcare Coverage

Thanks to the ACA, the number of uninsured individuals dropped from 46.5 million in 2010 to 26.7 million in 2016, with some of the largest coverage gains among individuals with lower incomes and people of color. Still, the number of uninsured individuals began to increase again in 2017, with 30 million U.S. residents lacking health insurance in 2020, and disparities among uninsured remaining, with most non-white groups more likely to be uninsured than white individuals. Of the 10.9 million people currently eligible for ACA marketplace coverage subsidies but unenrolled, 30% are Hispanic persons, 59% have a high school diploma or less, 42% are young adults, 16% live in rural areas and 11% do not have internet access at home.

These unequal rates in access to coverage indicate a need to prioritize ramping up outreach and enrollment assistance programs for those who are eligible for coverage but not yet enrolled in both the marketplace and Medicaid. Studies have shown the success of consumer assistance in getting people enrolled in coverage.<sup>28</sup> Increased investments in outreach for trusted, culturally competent partners in populations of focus will also help draw in more uninsured to evaluate their coverage options and eligibility for financial assistance. In 2019, a significant share of the population was unaware that the ACA provided subsidies for coverage and expanded Medicaid.<sup>29</sup> Because a significant share of the eligible but unenrolled are from groups that have been marginalized, greater investments in outreach and consumer assistance will go a long way in improving health equity by reducing barriers to coverage.

Additionally, data from marketplace issuers show about 17% of in-network claims are denied for marketplace enrollees, though rates by issuer vary from less than 1% to more than 50% percent. The however, marketplace issuer data also show that enrollees appeal less than 1% of all denied in-network claims, and very few of those will request an external review. Requesting an appeal requires time, resources and an understanding of insurance terms that few consumers have, particularly those of lower socioeconomic status, who have limited English proficiency, or for whom the information and process is otherwise inaccessible. Consumer assistance programs can help consumers overcome these barriers and successfully appeal denied claims. However, these programs have not received federal funding since 2012. Robust funding for consumer assistance programs in each territory, state and the District of Columbia would make assistance with appeals available across coverage types, including marketplace plans and employer-sponsored coverage.

#### Ensuring Medicaid Enrollees Have a Comprehensive Cessation Benefit

The American Lung Association urges the support and promotion of comprehensive tobacco cessation coverage to reduce disparities among those who smoke.<sup>33</sup> Studies show that individuals have the best chance of successfully quitting when they have access to both counseling and quit-smoking medications. The 2020 *Surgeon General's Report on Smoking Cessation* concluded that "insurance coverage for comprehensive cessation treatment with no barriers increases utilization, which in turn leads to higher rates of successful quitting and is cost-effective."<sup>34</sup>

Medicaid coverage of tobacco cessation is particularly important to improving health equity in tobacco control. Medicaid enrollees smoke at a rate over twice as high as those with private insurance. Comprehensive coverage without barriers is critical to helping the Medicaid population quit smoking. Removing barriers to accessing treatments is also critical. Administrative barriers such as prior authorization lead to patients delaying or abandoning treatment altogether.<sup>35</sup>

In addition to comprehensive coverage without barriers, individuals must have healthcare coverage in order to access cessation treatments. When states expand Medicaid under the ACA, individuals up to 138% of the federal poverty line have access to healthcare. Individuals in this expansion population are guaranteed coverage of preventive services, including tobacco cessation.<sup>36</sup>

According to the ACA and the FAQ guidance, Medicaid expansion plans and most private health insurance plans, including health insurance plans sold on the exchange, must cover a comprehensive tobacco cessation benefit – all seven medications and all three forms of counseling.<sup>37</sup> Plans also cannot impose cost-sharing or prior authorization. Data show, however, that not all states are adhering to this coverage requirement. In 2016, only nine of the 32 expansion states covered all seven medications and group and individual counseling.<sup>38</sup> In 2019, data showed that only 11 out of the 36 expansion states provided this coverage.<sup>39</sup> CMS must work with states to enforce the comprehensive tobacco cessation benefit in all exchange and Medicaid expansion plans to reduce tobacco-related health disparities

#### **Develop Cessation Methods to Reach Underserved Communities**

Most individuals disproportionately affected by tobacco experience several barriers to accessing cessation services. It is important for federal agencies to develop methods that meet members of underserved communities where they are. The Lung Association is encouraged by the National Texting Portal Pilot that was launched by CDC and the National Cancer Institute (NCI) in May 2021. CDC must ensure this portal is compatible across a range of devices as it will increase access to the services available on the portal for Medicaid enrollees and youth - two populations who smoke at significantly higher rates. Approximately 30% of Medicaid enrollees reported tobacco product use in 2019, which is much greater than those enrolled in private insurance (18%).<sup>40</sup> In 2020, approximately 23.6% of high school students used a tobacco product in the past 30 days before the survey was taken.<sup>41</sup>

Cell phone ownership is widespread among all racial and ethnic groups, regardless of education or income levels. 42 Most adult Medicaid beneficiaries (86%) own mobile technologies and use them for a variety of health purposes. 43 Over half of children in the U.S. own a smart phone by the age of 11 and 84% have teenagers have their own phones. 44 Additionally, it is important to note that those with lower socioeconomic status are less likely to have broadband connections at home and instead use cellphones to access the internet. 45

We are supportive CDC's and NCI's efforts to improve reach and uptake of cessation interventions by linking individuals interested in quitting to existing cessation resources that extend beyond the telephone, including texting services. We urge federal agencies to continue considering limitations and barriers underserved communities may face when developing interventions, guidelines and policies.

#### Improve Access to Safe, Healthy Housing

As OMB examines issues that contribute to structural inequities, we encourage the agency to take a holistic view of opportunities to improve equity by improving access to safe, healthy housing, particularly for residents who do not own their homes.

Everyone is entitled to a safe and healthy indoor environment. Many interventions to improve lung health and prevent lung disease have to do with housing. Effective indoor air quality measures protect primarily through the control and elimination of sources of pollution, radon testing and mitigation and the provision and maintenance of adequate, healthy ventilation. Too often, residents who do not own their homes have fewer opportunities to ensure healthy indoor air. This disproportionate impact on residents who rent or live in group settings has major implications for health. To the extent that OMB considers equity implications of individual policy issue areas, we highly encourage you to consider the wealth of disparities that flow from access to healthy housing.

#### **Stakeholder and Community Engagement**

Agencies can and must engage and empower individuals, especially those affected by agencies and their rulemaking processes, in the process so that the outcomes can meet the needs of the communities served. Currently, regulated industries have an advantage over the communities and people who may experience a disproportionate burden or a significant improvement in their health or well-being as a result of new rules. The rulemaking process must aim to be more transparent and prioritize the health and well-being of the public health and the population more widely.

#### Make Proposed Rules More Understandable

Agencies should provide a substantial summary at an accessible reading level on an easily accessible website for all economically significant rules. The summary should include how people can submit comments and any deadlines. We encourage OMB to explore additional opportunities to better inform members of the general public when a rule may impact them; for example, a proposal to reduce pollution affects not just polluting entities that must comply, but also anyone who breathes the improved air quality.

#### Allow Individuals to Submit Comments Via Email

Regulations.gov is a confusing and inaccessible website to navigate, making it harder for communities particularly affected by the proposed rule or the conditions the proposed rule seek to address. Agencies should create email addresses so that individuals can submit comments directly to agencies' rulemaking dockets without having to maneuver regulations.gov. Those emailed submissions should then become part of the record and be uploaded by the agency to the docket to ensure complete transparency.

For example, the Environmental Protection Agency has long had an email address so that individuals who are affected by the proposed rule can submit comments directly. Those individual comments are then added to the docket. However, the Food and Drug Administration has resisted the creation of an email address, making it much more difficult for communities impacted by their actions to engage in the rulemaking process.

#### Allow Individuals to Submit Comments in Languages Other Than English

OMB should require all agencies to accept comments in any language. Allowing comments to be submitted in languages other than English will help more individuals share their feedback on federal policies that impact their health and well-being. For example, the Department of Homeland Security's 2018 Notice of Proposed Rulemaking on Inadmissibility on Public Charge Grounds threatened access to Medicaid coverage and other public benefits for millions of immigrants – many of whom did not speak English – yet the Department only accepted comments in English. This barrier to commenting limits the federal government's ability to craft policies that serve non-English-speaking communities and effectively address the health and other disparities that they experience.

### Hold Virtual and In-person Public Hearings

We strongly encourage all federal agencies to hold both virtual and in-person public hearings when collecting public comments on proposed rules and other actions. The opportunity to present testimony in person on federal actions is important for an open and accessible process and informed policymaking. Agencies should also hold public hearings in physical locations convenient to populations who are experienced with the issue at hand, such as local pollution impacts. These hearings should also ensure that the hours are conducive to multiple segments of the public being able to participate, and that the sign-up and sign-in processes are clear and do not present additional barriers to public attendance.

We also call on agencies to hold additional, virtual public hearings that add to – rather than supplant – robust in-person hearings. And we urge agencies to learn from each other's best practices in removing barriers to public participation in rulemakings. For example, EPA's recent virtual information session preparing members of the public to participate in its listening sessions on oil and gas industry regulations could be an avenue for other agencies to explore. OMB could also provide guidance as to how to maximize public participation in public hearings.

#### Improve Tribal Consultation

Federal departments and agencies must consult with tribal governments prior to taking actions that have implications for Indian tribes. Tribal consultation requirements stem from the inherent

power of Indian tribes to self-govern and the unique political and legal relationship between the Indian tribes and the federal government. Effective tribal consultation will result in information exchange, mutual understanding and informed decision-making on behalf of the Indian tribes and the federal government. While several executive orders and federal regulations outline the requirements for consultation with Tribal Governments, compliance continues to be inconsistent.

We encourage OMB to facilitate and support improved methods and processes to meet the federal government's commitment to honor and respect tribal rights through tribal consultation. We also encourage you to highlight tribal consultation in federal register public notices, with information on the applicability of and steps taken to fulfill tribal consultation requirements.

#### Conclusion

The American Lung Association is fully committed to supporting investments and policies that eliminate health disparities caused by systemic racism and building health equity across all policy areas. We look forward to working with OMB and other federal agencies and programs to advance equity and support for underserved communities. Thank you for the opportunity to submit comments.

Sincerely,

Harold P. Wimmer

National President and CEO

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<sup>&</sup>lt;sup>1</sup> American Lung Association Public Policy Agenda, 117<sup>th</sup> Congress (2021-2022) <a href="https://www.lung.org/policy-advocacy/public-policy-agenda">https://www.lung.org/policy-advocacy/public-policy-agenda</a>

<sup>&</sup>lt;sup>2</sup> Fawcett, Stephen et al. "Building multisectoral partnerships for population health and health equity." *Preventing chronic disease* vol. 7,6 (2010): A118.

<sup>&</sup>lt;sup>3</sup> Evins, A. E., West, R., Benowitz, N. L., Russ, C., Lawrence, D., McRae, T., Maravic, M. C., Heffner, J. L., & Anthenelli, R. M. (2021). Efficacy and Safety of Pharmacotherapeutic Smoking Cessation Aids in Schizophrenia Spectrum Disorders: Subgroup Analysis of EAGLES. *Psychiatric Services*, *72*(1), 7–15. https://doi.org/10.1176/appi.ps.202000032

<sup>&</sup>lt;sup>4</sup> American Lung Association. Brief: Tobacco and Opioids. Accessed at: https://www.lung.org/assets/documents/tobacco/brief-on-tobacco-and-opioids.pdf

<sup>&</sup>lt;sup>5</sup> Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018. MMWR Morb Mortal Wkly Rep 2019;68:1013–1019. DOI: http://dx.doi.org/10.15585/mmwr.mm6845a2

<sup>&</sup>lt;sup>6</sup> American Lung Association Comments to HHS re Medicare FY2022 Psychiatric Facilities Prospective Payment System and Quality Reporting Updates (June 7, 2021). Accessed at: <a href="https://www.lung.org/getmedia/9c17e486-3990-45ca-8a5f-e1f90193c18f/american-lung-association-comments-fy22-psych-ipps-comments.pdf">https://www.lung.org/getmedia/9c17e486-3990-45ca-8a5f-e1f90193c18f/american-lung-association-comments-fy22-psych-ipps-comments.pdf</a>

<sup>&</sup>lt;sup>7</sup> Marynak K, VanFrank B, Tetlow S, et al. Tobacco Cessation Interventions and Smoke-Free Policies in Mental Health and Substance Abuse Treatment Facilities — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:519–523. DOI: http://dx.doi.org/10.15585/mmwr.mm6718a3

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