

July 27, 2023

The Honorable Xavier Becerra  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation**

Dear Secretary Becerra:

The American Lung Association is pleased to submit comments on the Request for Information: Draft Department of Health and Human Services (HHS) 2023 Framework to Support and Accelerate Smoking Cessation.

The American Lung Association is the oldest, voluntary public health organization in the United States. One of our four strategic imperatives is to create a tobacco-free future, and tobacco cessation is vital to that effort. Tobacco use is the leading cause of preventable death and disease in the United States, responsible for the deaths of 480,000 Americans annually.<sup>1</sup> An additional 16 million Americans live with a disease cause by tobacco.<sup>2</sup>

The Lung Association applauds the administration's focus on and desire to improve tobacco cessation and the need to ensure equity underlies this important work. There are disparities in who uses tobacco products and which products they use, however, data show that across demographics, including age, insurance status and education level, most smokers want to quit.<sup>3</sup>

The Lung Association is eager to work with HHS and other federal departments to support and accelerate smoking cessation. We offer the following comments on the request for information.

Eliminate Smoking and Cessation Related Disparities

*Finalize Rules Prohibiting Sale of Menthol Cigarettes and Flavored Cigars*

One of the most impactful things the administration could do is to finalize its proposed rules that would eliminate menthol cigarettes and flavored cigars from the marketplace. Menthol flavoring has been marketed and falsely perceived as a healthier alternative to non-menthol tobacco products.<sup>4</sup> For generations, the tobacco industry has intentionally targeted Black, Brown, youth, LGBTQIA+ and other communities with the marketing of menthol cigarettes. This false perception of less risk and relentless marketing has resulted in increased initiation with menthol cigarettes and high usage of menthol cigarettes, contributing to more tobacco-related death and disease as well as tobacco-related health disparities. Over 80% of Black Americans who smoke use menthol cigarettes.<sup>5</sup> Menthol cigarette use is also elevated among lesbian, gay and bisexual<sup>1</sup> individuals, 51% of LGB individuals who smoke use menthol cigarettes compared to 40% of heterosexual individuals who smoke.<sup>6</sup> A recent study quantified the disproportionate harms from menthol cigarettes to Black Americans, finding that menthol cigarettes were responsible for 1.5 million new smokers, 157,000 smoking-related premature deaths and 1.5 million life-years lost among Black Americans from 1980-2018.<sup>7</sup>

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<sup>1</sup> National data is not available for transgender individuals.

Menthol cigarettes have been found to increase both the likelihood of becoming addicted to cigarettes and the degree of addiction.<sup>8</sup> Research also 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>9</sup> This is seen in the available data around interest and success in quitting. Black persons who smoke report a greater interest in quitting and more past year quit attempts than their white counterparts. However, Black individuals have been less successful in quitting due in large part to their disproportionate use of menthol cigarettes, which are more difficult to quit.<sup>10</sup>

As would be expected, the proportion of smokers who say they would quit in response to a menthol cigarette prohibition is higher among Black people who smoke than other demographic groups. In the first 13-17 months of removing menthol cigarettes from the marketplace, one study estimates 923,000 people who smoke would quit, including 230,000 Black Americans.<sup>11</sup> This study, which evaluated Canada's law prohibiting the sale of menthol cigarettes, also concluded that removing menthol cigarettes from the marketplace was significantly associated with higher rates of quit attempts and quit success among menthol smokers compared to non-menthol smokers and may have helped to prevent relapse among menthol smokers who had quit smoking before the prohibition.

To maximize quitting, the proposed rules on menthol cigarettes and flavored cigars should be implemented concurrently on the same effective date. This will prevent the tobacco industry from selling menthol cigarettes posing as little cigars, which is a strategy the industry employed to try to blunt the effectiveness of Congress prohibiting all other flavored cigarettes besides menthol in 2009. A 2017 study using data from the 1999-2013 Youth Tobacco Surveys, analyzed the impact of the 2009 statutory prohibition of characterizing flavors in cigarettes on youth tobacco use. The researchers found that cigarette use declined significantly after 2009, whereas cigar and pipe tobacco use significantly increased.<sup>12</sup> Without a rule prohibiting the sale of flavored cigars, individuals who smoke menthol cigarettes may shift to using flavored cigars, especially menthol flavored little cigars, undermining the quitting that could occur from a menthol cigarette product standard.

As FDA, HHS and the administration advance these two proposed rules, we urge other HHS agencies, including the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and the Centers for Medicare and Medicaid Services (CMS), to loudly promote their plan to deliver culturally competent tobacco cessation services to menthol smokers to end their addiction entirely. This should include amplifying the continued partnerships with organizations that work to reduce tobacco use among communities disproportionately impacted by menthol cigarettes and flavored cigars. We would also recommend incorporating strategies from public health officials in Massachusetts to encourage quitting after its comprehensive state law ending the sale of flavored tobacco products, including menthol cigarettes took effect. They used unique strategies to reach menthol cigarette smokers through their state phone counseling service for tobacco users or state quitline among other strategies.

#### *Populations Experiencing Disparities*

Data consistently show poverty to be associated with higher tobacco use. The most recent data<sup>13</sup> available show people with a low income to poverty ratio smoking at a rate of 18.3% while their counterparts with a high income to poverty ratio smoke at a rate of 6.7%. Similarly, individuals enrolled in Medicaid smoke at a rate of 21.5%, while privately insured individuals

smoke at a rate of 8.6%. The smoking rate for this population has been stubbornly high and they have not seen the same reductions of tobacco use as their more affluent counterparts.

More needs to be done to support low-income individuals looking to make a quit attempt, recognizing they may need more support and interventions than other populations. HHS can prioritize Medicaid policies that help Medicaid enrollees that smoke quit. First, the Centers for Medicare and Medicaid Services (CMS) can work with state Medicaid programs to ensure all FDA-approved cessation medications and all three forms of counseling are covered without barriers for all enrollees in the state. CMS can work to quickly approve State Plan Amendments (SPAs) and 1115 waivers that expand access to cessation services and remove barriers. Additionally, CMS can deny and revoke 1115 waivers that impose a tobacco surcharge or implement non-smoker wellness incentive. These policies do not help people quit tobacco but discourage people from seeking care.<sup>14</sup>

Additionally, CMS should ensure the “Medical Assistance with Smoking and Tobacco Use Cessation (MSC-AD)” measure is included as part of the Behavioral Health Care Core Set. This encourages and will require states to collect these data. In turn the data will help identify gaps in treatment and can provide potential solutions.

Another population experiencing disparities in tobacco use are individuals with co-morbid behavioral health conditions. Individuals with behavioral health conditions smoke at a rate almost double that of their counterparts without a behavioral health condition (27.2% vs. 15.8%).<sup>15</sup> One of the impacts of this is people with behavioral health conditions that smoke die, on average, 15 years earlier than their counterparts with behavioral health conditions that do not smoke.<sup>16</sup>

Mental health treatment and substance abuse facilities are not providing tobacco cessation interventions for these populations: only 51.7% of mental health treatment facilities and 64.9% of substance abuse treatment facilities offered tobacco cessation counseling to their patients and approximately a third of these facilities provided cessation medications.<sup>17</sup> These facilities and the providers in these facilities need to be encouraged to help their patient population quit. One way HHS can influence this is by not removing TOB-2/2a (Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention) from reporting requirements in the proposed [FY 2024 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates](#).

The addiction to nicotine needs to be treated like any other addiction across the healthcare system, including in treatment recovery plans. As this can apply to treatment in the VA, Tricare, Medicare and Medicaid systems, the Lung Association encourages treatment of co-morbid behavioral health conditions, including addiction to nicotine. One example of something CMS can encourage states to do is to implement policies that require any facility, including behavioral health facilities to be tobacco-free indoors as a condition to accept Medicaid patients. The North Carolina Medicaid program has implemented a policy like this.

The Centers for Disease Control and Prevention (CDC) and the Office of the Surgeon General are currently working on a tobacco-related Surgeon General’s Report on Tobacco Use and Disparities. It is important that this report is finalized and made public by the end of 2023. It will serve as a roadmap both for identifying the issues specific populations face as it relates to

tobacco use and how to help those populations end their addiction to tobacco in ways that are culturally competent.

### Increase Awareness and Knowledge Related to Smoking and Cessation

#### *Awareness Campaigns*

Unfortunately, the Surgeon General's Report on smoking cessation found that four out of nine adult cigarette smokers who saw a healthcare professional in the past year did not receive advice to quit smoking.<sup>18</sup> Individuals who smoke need to be made aware of quit resources available to them. One way to achieve this is through public messaging campaigns.

The CDC's "Tips from Former Smokers" campaign is highly effective and has helped over a million people quit smoking.<sup>19</sup> To build upon the success of the campaign, it needs to run year-round. To accompany the campaign and increase the effectiveness of it, state quitlines need to be adequately funded to provide phone counseling and nicotine replacement therapy (NRT) to individuals looking to make a quit attempt.

The American Lung Association is deeply disappointed in the House FY2024 Appropriations bill that proposes to eliminate the Office on Smoking and Health (OSH). This CDC division runs the "Tips" campaign, supports state tobacco control programs with funding and technical assistance and publishes key surveillance data on tobacco use. The funding for OSH needs to be increased to allow the agency to continue their mission and expand upon their successful work.

#### *Integrating Cessation into Treatment*

Public awareness campaigns are one tool to improve awareness of tobacco cessation treatment. Integrating smoking cessation into diverse healthcare settings is another crucial strategy to increase awareness of tobacco cessation, prevent smoking-related illnesses and enhance public health outcomes. Employing proactive referral systems, engaging pharmacies and incorporating tobacco treatment into various care programs empower individuals in their journey to quit smoking and reduce the overall burden of smoking-related diseases. By adopting these approaches, healthcare systems can significantly contribute to the well-being of their patient populations and promote healthier communities overall.

Numerous studies have linked smoking to a wide range of diseases, highlighting the need for effective cessation strategies.<sup>20,21</sup> Opt-out systems, where patients are automatically enrolled in cessation programs unless they decline, have shown higher success rates in aiding smoking cessation compared to opt-in systems.<sup>22</sup> Proactively identifying smokers and referring them to cessation treatment enhances the chances of receiving necessary support to quit smoking successfully.<sup>23</sup>

Pharmacies serve as accessible points of contact for patients seeking health-related advice and medication, making them ideal partners in cessation efforts.<sup>24</sup> Involving pharmacies in smoking cessation allows patients to access information, counseling and FDA- approved cessation medications more conveniently.<sup>25</sup> Pharmacists' personalized advice and support play a crucial role in empowering patients' quitting journey.<sup>26</sup>

Integrating tobacco treatment into behavioral health and substance use disorder (BH/SUD) settings addresses the high smoking prevalence among individuals with mental health conditions and substance use disorders.<sup>27</sup> Dental and oral health professionals can identify people who smoke and offer cessation resources during routine dental visits, contributing to

cessation efforts.<sup>28</sup> Integrating tobacco treatment into chronic disease management programs, such as COPD and asthma management, leads to improved health outcomes.<sup>29</sup> And including tobacco treatment in youth-focused programs and pediatric settings helps prevent the development of nicotine dependence early on and fosters a healthy lifestyle among young individuals.<sup>30</sup>

The United States Preventive Services Task Force (USPSTF) gives lung cancer screening for the high-risk population a “B” grade, as it is effective in detecting lung cancer early and increases survival rates. The high-risk population is defined as: adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years.<sup>31</sup> One of the criteria of being high-risk is having a smoking history, including individuals who are still active smokers. Cessation interventions should be included as part of the lung cancer screening visit for individuals who smoke and meet the high-risk criteria for lung cancer screening. This is a key population to reach and at a pivotal moment.

#### *Promoting Insurance Benefits*

The Affordable Care Act (ACA) requires most health insurance plans to cover a comprehensive tobacco cessation benefit without cost-sharing to the patient. HHS and many departments within HHS can work with private insurance plans to encourage them to promote these benefits. The Center for Consumer Information and Insurance Oversight (CCIIO) can require plans sold on the exchange to disclose which tobacco cessation treatments are covered and if there are any barriers to access. Similarly, benefits should be disclosed to providers to encourage treatment. Additionally, CCIIO and CMS should work with the state quitlines to have insurance plans and Medicaid programs partner with the state quitlines to pay for the phone counseling. Additionally, private plans and Medicaid should make it easy for patients to use their insurance benefits to get cessation medications recommended by the quitline.

#### *Promoting a Comprehensive Public Health Framework to End the Tobacco Epidemic among Future Generations: A Youth-Centered Approach*

The surge in youth vaping is a pressing public health concern, raising alarm among health officials and policymakers. The level of youth addiction we are seeing is particularly disturbing. Among current youth e-cigarette users in 2022, 42.3% reported using e-cigarettes frequently on 20 of the past 30 days, including 46% of high school students and 20.8% of middle school students; daily use was reported among 27.6% of current e-cigarette users, including 30.1% of high school students and 11.7% of middle school students.<sup>32</sup>

To address this issue effectively, a comprehensive public health approach is necessary, and has been outlined in the American Lung Association’s Comprehensive Approach to Ending the Youth Vaping Epidemic Model, please see Appendix A.<sup>33</sup> By encouraging youth advocacy, promoting education, advocating for policy change, focusing on prevention, providing intervention and facilitating cessation services, we can create a supportive and tobacco-free environment that fosters the well-being of our youth and helps end the tobacco epidemic. This is especially important given the current lack of cessation options for youth, which we discuss in more detail below.

Providing students with access to counseling and support services helps those struggling with vaping addiction and creating peer support networks allows students to assist and encourage their peers in overcoming vaping addiction.<sup>34</sup> Offering evidence-based cessation programs within schools ensures accessible support for students looking to quit vaping.<sup>35</sup>

## Strengthen and Sustain Cessation Services and Supports

### *State Funding*

The overall goals regarding strengthening and sustaining cessation services and supports are appropriate, however, in order to achieve them state and local tobacco control funding needs to be increased. The bread and butter of tobacco control work, including tobacco cessation, takes place at the local and state levels. Not only do states need more funding, but the funding also needs to be consistent. Predictable and sustained funding allows states to plan out multi-year programmatic efforts, including cessation classes and quitline funding. States need to have the capacity to do this important work. Without adequate funding that will not happen.

The other side of this equation is needing a professional public health workforce, which we recognize CDC is also working to address. Since the COVID-19 pandemic, the public health workforce has been decimated. State tobacco control programs have not been immune to this trend. The lack of state and local public health workforce needs to be addressed, for both the larger public health community and specifically within the tobacco control community. Without the workforce and expertise, tobacco cessation work will not be successful.

### *Promoting Tobacco Treatment Plans*

Promoting evidence-based tobacco treatment plans that integrate FDA-approved cessation medication with behavioral counseling is essential to improve the success rates of quit attempts and reduce tobacco-related harm in the United States. The evidence supports the significant impact of behavioral counseling in boosting quit success rates by 50%,<sup>36</sup> while FDA-approved cessation medication offers effective solutions to manage withdrawal symptoms and cravings. By adopting this combined approach, healthcare providers can significantly enhance the support provided to individuals trying to quit smoking, ultimately contributing to a healthier and tobacco-free population.

The 2008 study conducted by Fiore et al. found that individuals who incorporated behavioral counseling into their tobacco treatment plan had a 50% higher success rate in quitting smoking compared to those who did not receive counseling.<sup>37</sup> Behavioral counseling can take various forms, including individual counseling, group counseling, telephone counseling and internet-based programs, offering individuals tailored support and strategies for quitting.<sup>38</sup> Nicotine replacement therapy (NRT), such as patches, gum, lozenges and nasal sprays, provide controlled doses of nicotine to reduce withdrawal symptoms and cravings, increasing the likelihood of successful cessation.<sup>23</sup> Additionally, an FDA-approved non-nicotine medication, bupropion, has shown efficacy in reducing withdrawal symptoms and improving quit rates;<sup>39</sup> additionally, varenicline, another FDA-approved medication, targets nicotine receptors in the brain, reducing withdrawal symptoms and cravings while blocking the rewarding effects of smoking.<sup>40</sup> The combination of FDA-approved cessation medication with behavioral counseling can double the likelihood of quitting successfully compared to unassisted quit attempts.<sup>41</sup> Studies suggest that individuals with dual dependence, such as nicotine and alcohol dependence, benefit significantly from the combined approach, promoting long-term abstinence.<sup>42</sup>

## Increase Access to and Coverage of Comprehensive High-Quality Cessation Treatment

### *Role of the Federal Government*

There are many levers the federal government has to increase access to and coverage of comprehensive high-quality tobacco cessation treatment. The United States Public Health

Service Guidelines define a comprehensive tobacco cessation benefit as the 7 FDA-approved cessation medications and three forms of counseling. This is also reaffirmed by the USPSTF, which gives an “A” recommendation to tobacco cessation treatment. However, in order to ensure this benefit is covered for all patients that need it, there are several key actions that the federal government can take.

First, standard Medicaid programs do not have to cover tobacco cessation counseling and can (and do) impose barriers to access treatment. As was previously discussed, Medicaid enrollees smoke at a rate more than twice that of their privately insured counterparts. It is incredibly important that this population has access to a comprehensive benefit without barriers. There is currently federal legislation, *Helping Tobacco Users Quit Act of 2023*, that would require a comprehensive benefit for standard Medicaid enrollees without cost-sharing. Data, collected by the American Lung Association, shows that most states cover tobacco cessation medications, but there are gaps in coverage around tobacco cessation counseling for the standard Medicaid population.<sup>43</sup> This bill should be passed as soon as possible so these benefits can be recognized by Medicaid enrollees.

Secondly, HHS should issue clear guidance on what health insurance plans and Medicaid expansion plans should be covering in terms of tobacco cessation treatment. In May 2014, HHS, along with the Departments of Treasury and Labor issued an FAQ ([Part XIX](#)) on tobacco cessation treatment coverage. This document must be clarified. All FDA-approved cessation medications need to be covered in addition to all three forms of counseling. HHS should consider increasing the number of quit attempts in order to better serve priority populations and that treatment should be accessible without barriers such as cost-sharing and prior authorization.

Thirdly, CMS should issue guidance to states in the form of a “Dear Medicaid Director” letter, outlining what flexibilities state Medicaid programs have regarding tobacco cessation treatment and what treatments should be covered. This could include: all FDA-approved medications and three forms of counseling need to be covered, encourage the removal of barriers to access treatment, types of providers that are able to bill for counseling, guidance for Managed Care Organizations (MCOs) to promote tobacco cessation benefits and guidance on what can be done to help people under 18 quit tobacco.

Lastly, HHS should develop guidance on standing orders for tobacco cessation. A barrier to access treatment, especially for the low-income population can be the need to get a prescription. A standing order can increase utilization and help get safe and effective treatments into the hands of the people that need them.

### *Court Challenges*

The *Affordable Care Act* (ACA) requires coverage of preventive services without cost-sharing in most private health insurance plans, including any plan sold on the exchange, and any Medicaid expansion plan. The ACA’s definition of preventive services includes anything given an “A” or “B” rating by the United States Preventive Services Taskforce (USPSTF); any vaccine recommended by the Advisory Committee on Immunization Practices (ACIP); and the Health Resources and Services Administration’s (HRSA) Bright Futures for Children recommendations and Women’s Preventive Services Initiative recommendations. Tobacco cessation receives an “A” grade from the USPSTF for all seven medications and all three forms of counseling.

A recent federal court case, *Braidwood v Becerra*, threatens access to preventive services without cost-sharing. US District Judge O'Connor ruled in September 2022 that the USPSTF coverage requirement must be vacated and cannot be enforced by the U.S. Department of Health and Human Services. On March 30, the judge ruled that all ACA-compliant plans including employer-sponsored and Medicaid expansion plans are no longer required to cover USPSTF preventive services without cost-sharing.

This lawsuit threatens progress on the coverage of tobacco cessation treatment, along with many other treatments and screenings, including lung cancer screening. We urge HHS to vigorously defend this provision of the ACA.

### *Quality Measures*

A common idiom in healthcare is “what gets measured, gets done.” Quality measures are the way healthcare is measured, and sometimes paid for. Quality measures for tobacco cessation are time-consuming to collect and can create additional paperwork, as they currently involve chart extraction. However, quality measures, especially when tied to payment, change provider behavior. HHS should encourage the development of an eMeasure for tobacco cessation that includes tobacco use status, advice to quit and treatment provided. This measure could be used more robustly throughout the federal government, including in Medicare Inpatient Psychiatric Facilities Prospective Payment System-Rates, Medicare Inpatient Facilities Prospective Payment System-Rate and in the Universal Foundation of Quality Measures.

### *Integrating Cessation in EHRs*

Integrating evidence-based cessation strategies into health systems is crucial to effectively address the needs of people who smoke, and the role of electronic health records (EHRs) as a catalyst for advancing tobacco cessation efforts within health systems is critical. As stated above, the development of an eMeasure that does not require chart extraction is imperative. Including tobacco-use status in core sets across all EHRs can significantly increase the identification of patients who use tobacco products and facilitate effective interventions to encourage and assist with tobacco cessation. The seamless identification and documentation of tobacco use status for every patient at every visit offer a simple, low-cost intervention that prompts clinicians to inquire about tobacco use and provide necessary recommendations to support individuals in their quit journey.

The integration of tobacco-use status in EHRs prompts clinicians to inquire about patients' tobacco use and offer cessation recommendations during routine care,<sup>44</sup> and the availability of patients' tobacco use status enables tailored recommendations and interventions based on individual needs and preferences.<sup>45</sup> Leveraging EHRs for tobacco cessation interventions minimizes additional costs and resources, making it a feasible strategy for health systems.<sup>46</sup> Integrating tobacco cessation into EHRs ensures that clinicians consider tobacco use as an essential component of patients' overall health and well-being.<sup>47</sup>

## Expand Surveillance of Smoking and Cessation Behaviors and Strengthen Performance Measurement And Evaluation

### *Tracking Utilization*

The Lung Association encourages CMS to collect data from state Medicaid programs, including managed care programs on the utilization of tobacco cessation treatments, including all 7 FDA-approved medications and all three forms of counseling. This would allow CMS to identify where



individuals are accessing cessation and where more promotion is needed or where barriers to access need to be removed.

### *Evaluation Metrics in EHRs*

Integrating evidence-based cessation strategies into health systems and utilizing electronic health records (EHRs) to expand surveillance and evaluation, enhancing performance measurement and utilization tracking is crucial to achieve this goal. By incorporating evaluation metrics within EHRs, health systems can strengthen their performance measurement and evaluation processes. The proposed evaluation metrics encompass key indicators, such as tobacco use status documentation, tobacco product usage, brief intervention provision, program enrollment, successful quitting rates, and maintenance of a tobacco-free lifestyle. Additionally, tracking utilization data within EHRs can provide valuable insights to optimize the effectiveness of tobacco cessation programs and promote tobacco-free living.

The Lung Association would like to suggest the following as a framework for evaluation metrics for tobacco cessation:

1. Documented Tobacco Use Status: Recording tobacco use status for each patient in EHRs enables healthcare providers to track smoking behaviors and tailor interventions accordingly,<sup>48</sup> including the documentation of the type of Tobacco Products Used: Identifying the specific tobacco products used by individuals documented in EHRs helps tailor cessation approaches for different user groups.<sup>49</sup>
2. Brief Intervention Provision: Tracking the number of individuals receiving a brief tobacco cessation intervention provides insights into the frequency and effectiveness of these interventions in routine clinical practice.<sup>50</sup>
3. Program Enrollment and Completion:
  - a. Acceptance of Treatment and Referral: Monitoring the number of individuals accepting treatment and referral into a cessation program allows for evaluating the effectiveness of referral processes.<sup>51</sup>
  - b. Successful Program Enrollment: Tracking the number of individuals successfully enrolled in tobacco cessation programs measures program accessibility and efficacy.<sup>52</sup>
  - c. Completion Rates: Evaluating the number of individuals successfully completing tobacco cessation programs assesses program effectiveness in promoting sustained quitting.<sup>53</sup>
  - d. Successful Quitting Rates and Maintenance:
4. Successful Quitting through Programs:
  - a. Monitoring the number of individuals who quit tobacco use through the completion of a cessation program demonstrates program success in achieving its goals.<sup>54</sup>
  - b. Maintenance of Tobacco-Free Lifestyle: Tracking the number of individuals maintaining tobacco abstinence for at least 6 months post-cessation program assesses long-term success rates.<sup>55</sup>
5. Utilization Tracking within EHRs:
  - a. Identifying Usage Patterns: Tracking utilization data within EHRs allows health systems to identify patterns in program usage and tailor interventions accordingly.<sup>56</sup>
  - b. Optimize Intervention Delivery: Utilization data can provide insights into the most effective intervention delivery methods and improve resource allocation for tobacco cessation programs.<sup>57</sup>

## Promote Ongoing and Innovative Research to Support and Accelerate Smoking Cessation

### *New Cessation Medications*

It has been 17 years since a tobacco cessation medication has been approved by the FDA. The Center for Drug Evaluation and Research (CDER) [must be proactive to solicit manufacturers to develop new medications to treat tobacco use](#). The National Institutes of Health (NIH) could also encourage the development of cessation drugs. The tobacco control community needs additional resources to help patients quit.

### *Youth Cessation*

While the strategic plan is specific to adult combustible tobacco use, the Lung Association believes the administration is missing an opportunity not to mention youth cessation. As mentioned above, youth tobacco use rates have fluctuated dramatically over the last 5 years and remain at high levels.

The American Lung Association co-leads the National Youth Cessation Workgroup, which aimed to find actionable steps to help kids and teenagers quit tobacco. The group identified many challenges in achieving this, including running clinical trials with youth. However, despite the challenges with youth cessation, action must be taken especially in light of the high rates of youth tobacco use. The Lung Association encourages NIH to be a leader in this area. Additionally, CMS should develop guidance for states on state Medicaid programs covering NRT off-label, per the [American Academy of Pediatrics Clinical Considerations](#). Lastly, once the evidence is sufficient, the Lung Association encourages USPSTF to consider the evidence for youth cessation and make a recommendation.

## Additional Actions for HHS to Take to Advance this Framework

### *CDC Should Update “Best Practices for Comprehensive Tobacco Control Programs”*

CDC’s [Best Practices for Comprehensive Tobacco Control Programs](#) is an evidence-based guide for states on how to build, implement and maintain effective state programs to prevent and reduce tobacco use. It specifically includes a section on Cessation Interventions, which currently recommends focusing on three broad goals: 1) promoting health systems change; 2) expanding insurance coverage of proven cessation treatments; and 3) supporting state quitline capacity. Originally published in 1999, it has gone through several updates since then, the latest one having been released in 2014. The Lung Association strongly encourages CDC to update this essential and comprehensive guide for states as soon as possible to help bring knowledge to bear from the past ten years about state efforts to quit tobacco use with a focus on health equity and culturally competent tobacco cessation services. This knowledge can then be used by states to promote and deliver tobacco cessation treatments and services more effectively.

### *FDA Should Implement the Track and Trace System as was Required by Federal Law*

FDA must implement the track-and-trace system it was mandated to do as part of the Family Smoking Prevention and Tobacco Control Act, the 2009 law that gave FDA the authority to regulate tobacco products. There is currently an outstanding [citizen petition](#) that the Lung Association and several partners filed in 2013 to implement such a track and trace system to which FDA has yet to respond. Under this system, FDA and other law enforcement authorities would be able to identify the source and distribution history of product packages and increase the effectiveness of law enforcement. While Congress mandated the track and trace system for cigarettes, it should include all tobacco products. This would have great value in enforcing

compliance with product standards such as the proposed menthol cigarettes and flavored cigars prohibitions, prevent an illegal market and maximize the quitting of tobacco use that could result from such product standards.

*CDC Should Review State Tobacco Control Strategic Plans*

HHS and CDC specifically has an opportunity to provide guidance to state tobacco control programs in the United States by reviewing state tobacco control strategic plans and identifying proven-effective strategies to significantly decrease tobacco-related morbidity and mortality across their states. By utilizing the framework of the [National Tobacco Control Program \(NTCP\) goals](#), which use evidence-based approaches to achieve specific objectives, including promoting quitting among adults and youth and advancing health equity by identifying and eliminating commercial tobacco product-related inequities and disparities.

*HHS Should Update the 2008 Guideline for Treating Tobacco Use and Dependence*

There is an imperative need for HHS to support an update to the [Treating Tobacco and Dependence Guideline](#), which provides essential recommendations for healthcare professionals in delivering effective tobacco cessation interventions. It was last updated in 2008 before the popularity of e-cigarettes exploded, and much knowledge has been gained on these topics since then. By incorporating the latest research findings and advancements in tobacco cessation strategies, an updated version of the guidelines can better equip healthcare professionals and tobacco control advocates to combat the tobacco epidemic and improve health outcomes for individuals across the nation.

*HHS Should Advance a Comprehensive Whole-Person Approach to Tobacco Cessation*

To effectively address tobacco use, a comprehensive whole-person approach is essential. By identifying areas where tobacco cessation education, intervention, and treatment can be further integrated, HHS and its agencies can collectively strengthen tobacco cessation efforts. Integrating and prioritizing cessation initiatives across IHS, HRSA, Center for Faith-based and Neighborhood Partnerships, AHRQ, and SAMHSA will promote equitable access to evidence-based cessation support, improve public health outcomes, and advance the nation towards a tobacco-free future.

Conclusion

The American Lung Association is excited about the prospects of the HHS draft Strategic Plan on Cessation. Tobacco is the leading cause of death and disease in the United States. More can be done and needs to be done to help tobacco users quit. If implemented correctly, this could help millions of people in the United States.

The American Lung Association looks forward to partnering with HHS and the other agencies to work on making this plan a reality. Thank you for the opportunity to submit comments.

Sincerely,



Harold P. Wimmer  
National President and CEO

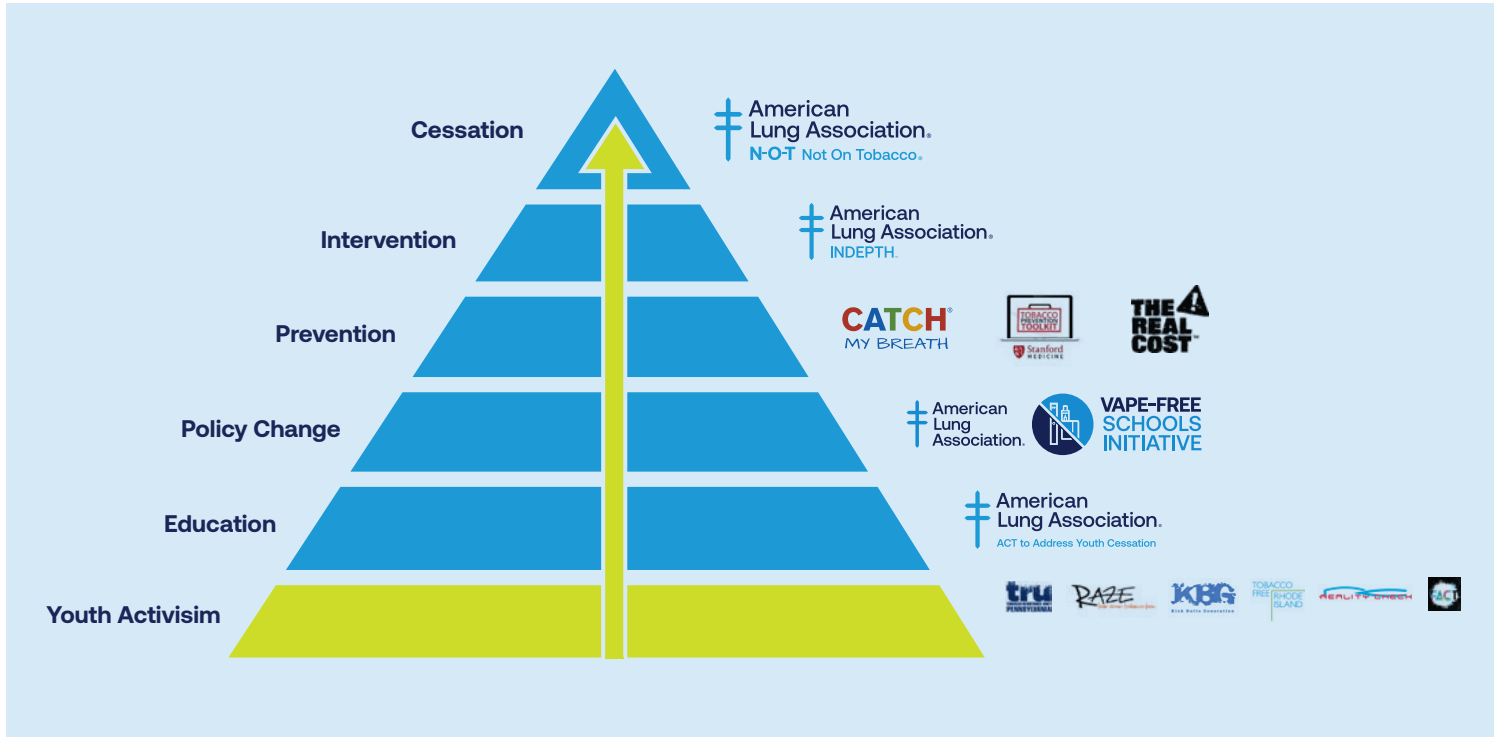
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**Appendix A:**  
American Lung Association's  
Comprehensive Approach to Ending the Youth  
Vaping Epidemic Model

The American Lung Association recommends a multi-component comprehensive public health approach to addressing the youth vaping epidemic through strategies inclusive of systems change, education, intervention and cessation.



**Component 1:** Promoting youth activism through a student engagement program, such as Delaware’s Kick Butts Generation, FACT in Wisconsin, Pennsylvania’s Tobacco Resistance Unit (TRU), Reality Check in New York, Tobacco-Free Rhode Island or West Virginia’s RAZE, a statewide youth-led movement to work towards creating tobacco-free futures for all. Youth members are between the ages of 12 and 18 and include students who care about the impact of tobacco use on public public health, seek to stay informed about the real dangers of vaping and smoking and find creative ways to share that knowledge with the world.

**Component 2:** Educating all school counselors, teachers, coaches and administration in the American Lung Association’s ACT to Address Youth Cessation Training, a one-hour on-demand, online course that provides an overview for school personnel in youth/adolescent supportive roles in conducting a brief intervention for teens who use tobacco. Based on the American Academy of Pediatrics’ Youth Tobacco Cessation: Considerations for Clinicians, the session outlines the steps of Ask, Counsel, Treat, and provides guidance, support and best practices for effectively delivering ACT as a brief intervention for adolescents who identify as currently using tobacco, including e-cigarettes. Complete the course here: <https://lung.training/courses/act-to-address-youth-cessation.html>





**Component 3:** Conduct an assessment of your current tobacco-free campus policy at all school building locations through American Lung Association’s Vape Free Schools Initiative to identify gaps that may exist in your current policies on school buildings and campuses grades K-12 through American Lung Association’s Vape Free Schools Initiative and determine strategies for strengthening it to provide a comprehensive public health approach to countering the e-cigarette epidemic. Take the assessment here: <https://lung.training/courses/policy-assessment-and-toolkit.html>

**Component 4:** Prevention education for grades 5-12 through the evidence-based vaping prevention program such as [CATCH My Breath](#), the [Stanford Medicine’s Tobacco Prevention & Vaping Toolkit](#) or the [FDA’s The Real Cost of E-Cigarette Prevention Campaign](#).

**Component 5:** Intervention programming for identified teens who use tobacco and tobacco-free campus policy student violators through [American Lung Association’s INDEPTH® program](#), an evidence-based alternative to suspension/citation program for grades 5-12. Training to deliver this adult-led in-person intervention program is available through <https://lung.training/courses/indepth.html>. An English-language online on-demand version is currently in development and will be launched for the 2023/2024 school year. A Spanish-language online on-demand version will be made available shortly after.

**Component 6:** Cessation programming for teens who use tobacco wanting to quit made available through [American Lung Association’s Not-On-Tobacco®](#), a voluntary cessation program tailored specifically for youth ages 14-19 and available either via a [trained and certified](#) adult-facilitator-led group class in-person or virtually or self-paced online at [NOTforMe.org](https://NOTforMe.org). A Spanish-language online on-demand version will be launched and made available for the 2023/2024 school year.

**Call to Action:** The American Lung Association invites all school administration to partner with us in implementing this comprehensive multi-tiered public health approach to addressing the e-cigarette epidemic among our youth throughout the school district and target communities you serve. We are here to support you with the evidence-based and proven-effective programs and resources necessary in creating a tobacco-free future for our next generations. Together we can make a difference. For more information, please contact us at [youthprograms@Lung.org](mailto:youthprograms@Lung.org).