AMERICAN LUNG ASSOCIATION.

January 3, 2017

The Honorable Sylvia Matthews Burwell
Secretary, U.S. Department of Health & Human Services
200 Independence Ave. SW
Washington, DC 20201

The Honorable Thomas E. Perez
Secretary, U.S. Department of Labor
200 Constitution Ave. NW
Washington, DC 20210

The Honorable Jacob J. Lew
Secretary, U.S. Department of the Treasury
1500 Pennsylvania Ave. NW
Washington, DC 20220

Dear Secretary Burwell, Secretary Perez and Secretary Lew:

The Affordable Care Act (ACA) has made great strides in focusing healthcare in the U.S. on preventing diseases in addition to treating them. The requirement that all non-grandfathered private health insurance plans cover preventive services given an 'A' or 'B' rating by the U.S. Preventive Services Task Force (USPSTF) is a key driver of this change.

There is no greater way to reduce preventable disease than by helping smokers quit. Smoking is responsible for almost half a million deaths each year. Additionally, over 40 percent of all cancers, 90 percent of COPD and 30 percent of cardiovascular disease is attributable to smoking. The human cost of tobacco is far too high. And the financial impact is also high: in 2014, the Surgeon General estimated that economic cost associated with smoking, including secondhand smoke was almost $300 billion a year.

Smoking prevalence is not spread evenly among all Americans. Data consistently show that lower income individuals smoke at higher rates than Americans who fall into higher socio-economic levels. These low-income individuals are now able to access quality affordable healthcare, perhaps for the first time in their lives either through Medicaid expansion or on the exchanges. To recognize the full potential of the ACA at preventing disease and improving health, preventive services must be covered. Tobacco cessation

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is a low-cost, high impact preventive service that will dramatically improve the health of those who quit smoking.

Helping Smokers Quit Saves Lives and Money
The impact of smoking and exposure to secondhand smoke still plague the United States, but there are proven effective treatments for helping smokers quit, saving both lives and money.

In September 2015, the USPSTF issued an update to its recommendations concerning tobacco cessation. After USPSTF released its updated clinical recommendations, 39 health and medical groups, including the American Lung Association, asked your departments to update its May 2014 Frequently Asked Question (FAQ) concerning a comprehensive tobacco cessation benefit to reflect the updated USPSTF recommendation.

The American Lung Association is deeply disappointed that the your departments failed to act on the September 2015 U.S. Preventive Service Task Force grade "A" recommendation that stated that all treatment options for tobacco cessation should be offered without barriers. The failure to act to update the May 2014 FAQ further delays much needed clarity on this issue and also delays access to quit smoking treatments for smokers.

In response to the October 27 request for comment, the American Lung Association shares the following comments in response to the questions posed by the tri-departments:

a) As the FAQ states at the introduction, the "Public Health Service Act (PHS Act) section 2713 and its implementing regulations relating to coverage of preventive services require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to cover **without the imposition of any cost-sharing requirements**, the following items or services: Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved…" (Emphasis added)

   The 2015 USPSTF recommendations clearly state that "Both intervention types (pharmacotherapy and behavioral interventions) are effective and recommended; combinations of interventions are most effective, and all should be offered. ***The best and most effective combinations are those that are acceptable to and feasible for an individual patient; clinicians should consider the patient's specific medical history and preferences and offer and provide the combination that works best for the patient."*** (Emphasis added)

   Based on the clear reading of both the law and the 2015 recommendations, it is unequivocal that if provider prescribes a behavioral or pharmacotherapy treatment to his or her patient that is consistent with the guidelines, then it must be covered by plans and issuers without cost-sharing or further medical management techniques. The USPSTF is clear that for the best chance of successful quit attempt, clinicians are to act based on individual patient's medical

history and needs. As a result, all seven categories of FDA-approved pharmacotherapies alone or in combination must be covered if a provider prescribes the treatment for his/her patient.

It is equally clear that because the USPSTF recommendations state that the *clinician* is to consider the specific patient's medical history that stepped therapy and/or prior authorization are not consistent with the USPSTF recommendations and therefore should not be permitted. Requiring stepped therapy does not allow a prescriber to take into consideration a smoker's medical history and is therefore not consistent with the USPSTF recommendations. Prior authorization is also inconsistent because it puts the treatment decision in the hands of the plan or payer – and not the clinician.

b) According to previous Tri-Department guidance[1], reasonable medical management techniques concerning frequency, method, treatment or setting for the provision of the service may only be applied if the U.S Preventive Services Task Force is silent. Otherwise, reasonable medical management techniques cannot be used to create barriers to the USPSTF recommendations.

   i. There is no specific mention in the USPSTF recommendations regarding the number of times a smoker should be supported with an evidence-based quit attempt per year. Because tobacco products are addictive, many smokers need several attempts to successfully quit. The American Lung Association supports - at a minimum – at least two quit attempts per year.

      FDA drug approvals clearly state how long a drug should be used by the patient: 12 weeks for the nicotine patch and nicotine gum; 14 weeks for bupropion; and 6 months for varenicline and the other nicotine replacement therapies including the lozenge, nasal spray and inhaler. Plans and issuers should be required to cover the treatments within the parameters for use as approved by FDA. The 2015 recommendation refers providers back to the FDA recommended duration of use. To limit duration to less than the dosing regimens on the package inserts would be counter to the USPSTF recommendation.

   ii. The USPSTF clearly states that all categories of FDA-approved medications – either individually or in combination – are effective to help smokers quit and are part of the 2015 recommendation. It is therefore incumbent that all seven medications, either individually or in combination, must be covered without cost-sharing, as required by the ACA.

      The payer or issuer does have discretion within each of the seven categories as to which medication they may cover. For example, when there are generics or multiple brands available within one of the seven categories, the plan or issuer may determine which one it will cover without cost-sharing.

iii. Regarding behavioral interventions: The USPSTF states "Effective behavior interventions include in-person behavior support and counseling, telephone counseling, and self-help materials." The 2015 USPSTF state that regarding counseling, patients should receive at least 4 in-person counseling sessions, lasting at least 10 minutes and that phone counseling can be effective with at least 3 telephone calls.

Plans and issuers must provide all three types of behavior interventions without cost-sharing. They must cover at a minimum the specific number of sessions outlined by the USPSTF for in-person individual, group and telephone counseling. However, plans and issuers would have discretion what additional interventions are covered beyond the USPSTF specifications

The American Lung Association strongly urges that a new FAQ be issued as soon as possible so that millions of American smokers have access to tobacco cessation treatments as outlined by the USPSTF. Thank you for your consideration.

Sincerely,

Harold Wimmer
National President and CEO

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[1] FAQS About Affordable Care Act Implementation Part XXVI. Accessed November 15, 2016. https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf