



SAVING LIVES AND ADVANCING
RESEARCH BY EMPOWERING
THOSE LIVING WITH AND
AT RISK FOR LUNG CANCER.

LungCancerAlliance.org

1700 K Street NW, Ste 660
Washington, DC 20006

December 22, 2016

VIA Electronic Submission to:
marketreform@cms.hhs.gov

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 Matthew, 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 diseases than by helping smokers quit. Lung Cancer Alliance (LCA) focuses solely on the needs of the lung cancer community and has led efforts to bring a more coordinated, comprehensive and compassionate public health strategy to those either living with or at risk for the disease. Working to advance prevention, early detection and treatment research strategies in a continuum of care, LCA advocates for equitable and affordable access to breakthrough preventive services to allow patients to have quality, longer lives, without coverage prohibitive medical expenses.

In September 2015, the USPSTF issued an update to its recommendations concerning tobacco cessation. In response, 39 health and medical groups urged the tri-departments to issue a new Frequently Asked Question (FAQ) concerning a comprehensive tobacco cessation benefit to reflect the updated USPSTF recommendation.

In response to the October 27, 2016 request for comment, below are the following comments in response to the questions posed by the tri-departments:

- a) The Departments asked whether all seven categories of FDA-approved pharmacotherapy interventions must be covered without cost sharing when prescribed by a health care provider. Based on our assessment of the statutory requirements and the 2015 USPSTF recommendation, we believe the answer is yes. As the FAQ itself 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...”

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 – as the USPSTF is clear that the clinicians are to act based on the individual patient and their medical history and preferences. As a result, all seven categories of FDA-approved pharmacotherapies alone or in combination must be covered if a prescriber issues a prescription 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, as it means that the plan or payer – and not the clinician – is determining the combination or therapy.

- b) The Departments asked if plans and issuers may use reasonable medical management techniques to: i) limit the number of quit attempts per year or the duration of the interventions prescribed; ii) manage the categories of FDA-approved pharmacotherapy

interventions that may be covered without cost sharing when used in combination; or iii) limit the types of behavioral interventions that are covered without cost sharing. According to previous Tri-Department guidanceⁱ, 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 regarding the number of times a smoker should be supported with an evidence-based quit attempt per year. However, USPSTF notes that “most smokers make several serious attempts to quit before achieving permanent abstinence.” The most reasonable interpretation of this statement would be for plans and issuers to cover more than one quit attempt per year. The Office of Personnel Management requires Federal Employees Health Benefits (FEHB) plans to cover at least two quit attempts a year and the Centers for Medicare and Medicaid Services requires Medicare Part B coverage of two quit attempts per year. Recognizing the number of times most smokers try but are unsuccessful with their quit attempts, our organization supports a minimum of two quit attempts per year.ⁱⁱ

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.

- ii. The USPSTF clearly states that all categories of FDA-approved medication – either individually or in combination -- are effective. It is therefore incumbent that the payer or issuer only have discretion to apply medical management within the seven categories and may not deny coverage of any of the seven categories of FDA-approved medications. 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 states 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.

While all plans and issuers must provide all three types of behavior interventions without cost-sharing and must cover at least the specific number of sessions outlined by the USPSTF for in-person and telephone counseling, plans and issuers would have discretion beyond that.

LCA recommends 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. Please feel free to contact our Director of Health Policy, Elridge Proctor at 202-742-1427 or Eproctor@lungcanceralliance.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "Laurie Fenton-Ambrose". The signature is written in a cursive style with a large, flowing "L" at the beginning.

Laurie Fenton-Ambrose
President and CEO
Lung Cancer Alliance

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>

ⁱⁱ See, Chaiton, Michael, et al. "Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers." *BMJ Open* 6.6 (2016): e011045