











American Academy of Pediatrics

































































November 12, 2015

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

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

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

On September 21, 2015, the USPSTF issued an update to its recommendations concerning tobacco cessation. The undersigned organizations write today to ask you to issue a new tri-agency Frequently

Asked Question (FAQ) concerning a comprehensive tobacco cessation benefit to reflect this updated USPSTF recommendation.

Background

Tobacco cessation interventions have been required coverage since 2010 under the ACA. However, our organizations and our constituents have seen large inconsistencies in how the requirement is implemented in plans. On February 19, 2014, 30 tobacco control and public health groups including many of the same undersigned here, sent a letter to then Secretary Sebelius urging the Department of Health and Human Services (HHS) to clarify what is required to be covered for tobacco cessation as a preventive service under the ACA. In this letter, the groups identified a 2012 study conducted by Georgetown University that found "many health insurance plans are failing to provide the coverage mandated by the ACA for treatments to help smokers and other tobacco users quit. Specifically, researchers found that only four of the 39 private plans analyzed clearly covered a full-range of evidence-based tobacco cessation services." This study confirmed mounting anecdotal evidence of confusion among health insurers, healthcare providers and tobacco control professionals regarding which tobacco cessation treatments were required to be covered under the ACA.

As you are aware, on May 2, 2014, the U.S. Departments of HHS, Labor and Treasury issued ACA Implementation FAQs XIX. Question five of this FAQ stated:

Q5: The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. What are plans and issuers expected to provide as preventive coverage for tobacco cessation interventions?

As stated earlier, plans may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline regarding that preventive service. Evidence-based clinical practice guidelines can provide useful guidance for plans and issuers. The Departments will consider a group health plan or health insurance issuer to be in compliance with the requirement to cover tobacco use counseling and interventions, if, for example, the plan or issuer covers without cost-sharing:

- 1. Screening for tobacco use; and,
- 2. For those who use tobacco products, at least two tobacco cessation attempts per year. For this purpose, covering a cessation attempt includes coverage for:
 - Four tobacco cessation counseling sessions of at least 10 minutes each (including telephone counseling, group counseling and individual counseling) without prior authorization; and
 - All Food and Drug Administration (FDA)-approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen when prescribed by a health care provider without prior authorization.

This guidance is based on the Public Health Service-sponsored Clinical Practice Guideline, Treating Tobacco Use and Dependence: 2008 Update, available at: http://www.ahrq.gov/professionals/clinicians-providers/quidelines-recommendations/tobacco/index.html#Clinic.

New USPSTF Recommendation on Tobacco Cessation

On September 21, 2015, the USPSTF released an updated <u>recommendation statement</u> "Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions." The statement includes the following recommendation:

The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy for cessation to adults who use tobacco. (A recommendation)

This updated recommendation summary statement makes it clear that the USPSTF considers tobacco cessation treatment as a preventive service that includes behavioral interventions (counseling) **and** pharmacotherapy interventions (medications). Furthermore, the Clinical Considerations section of the statement clearly states that effective behavioral interventions included in the Task Force recommendation are individual, group and telephone counseling (see pg. 5 of the <u>full recommendation statement</u>). In the same section, the Task Force includes "bupropion SR, varenicline and NRT (including nicotine transdermal patches, lozenges, gum, inhalers or nasal spray)" as the pharmacotherapy interventions included in the 'A' recommendation (see pg. 5 of the <u>full recommendation statement</u>).

Furthermore, the Task Force states that [emphasis added]

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. (see pg. 4 of the full recommendation statement)

The USPSTF recommendation, particularly in the passages quoted above, has clearly established that its recommendation includes a comprehensive tobacco cessation benefit, including all FDA-approved cessation medications, and three types of counseling. As the 2015 USPSTF recommendations are different from previous versions and include clearer and more specific details regarding recommended tobacco services, it is timely and appropriate that the Departments of Health and Human Services, Labor and Treasury issue an updated FAQ on insurance coverage of tobacco cessation interventions as a preventive service.

Recommendations for a New FAQ

The FAQ on tobacco cessation treatment issued in 2014 listed the treatments recommended by USPSTF. In light of the 2015 USPSTF recommendation, the Departments must provide even greater clarity on what health plans are required to cover. The undersigned groups urge your departments to issue an updated FAQ that aligns with the 2015 USPSTF recommendation, making it clear that health plans must cover all treatments listed in the FAQ and recommended by USPSTF, and that **all** treatments must be offered with no cost-sharing or prior authorization. This can be accomplished by making the following two changes to the 2014 FAQ:

1. Remove the ambiguity and clearly articulate what constitutes coverage. Delete the "for example" phrase in the 2014 FAQ: "The Departments will consider a group health plan or health insurance issuer to be in compliance with the requirement to cover tobacco use counseling and interventions, if, for example, the plan or issuer covers without cost-sharing..." The ACA clearly states that all USPSTF 'A' or 'B' recommended services shall

be covered without cost-sharing. Deleting this phrase will further clarify for payers what is required under the law without cost-sharing.

2. Clarify that each tobacco cessation treatment must be covered with no cost-sharing, by including the following language: "Updated USPSTF recommendations (2015) clearly state that all FDA-approved medications and behavioral interventions must be covered with no cost-sharing." A clear, direct statement of this in the FAQ will remove any remaining confusion on this point and indicate to all plans that they may not charge cost-sharing for any of the seven FDA approved cessation medications or the three recommended counseling services.

As you know, the ACA (42 U.S. Code § 300gg–13) requires all preventive services to be covered without cost sharing in group and individual health insurance plans; and all preventive services be covered without cost sharing in qualified health plans (42 U.S. Code § 18022). A new FAQ must also come with a new commitment to enforcing these ACA provisions. Our organizations are concerned that without this commitment, implementation of these requirements by plans, employers and state regulators will continue to be inconsistent.

Issuing a new FAQ that clearly and succinctly reflects the 2015 USPSTF recommendations as we have recommended above will make huge strides toward ensuring that all tobacco users in this country have consistent access, in all covered health plans, to the help they need to quit. It will save lives and reduce the health costs of tobacco-caused disease. Our organizations stand ready to work with you in these efforts, and thank you for considering our recommendations.

Sincerely,

Action on Smoking and Health
Altarum Institute
American Academy of Family Physicians
American Academy of Oral and Maxillofacial
Pathology
American Academy of Oral Medicine
American Academy of Otolaryngology —
Head and Neck Surgery
American Academy of Pediatrics
American Association for Cancer
Research
American Association for Respiratory Care
American Cancer Society Cancer Action
Network
American College of Cardiology

American College of Cardiology
American College of Occupational and
Environmental Medicine
American College of Preventive Medicine
American Congress of Obstetricians and
Gynecologists
American Heart Association
American Lung Association
American Medical Association
American Psychological Association

American Public Health Association

American Society of Addiction Medicine American Society of Clinical Oncology **American Thoracic Society** Association of State and Territorial Health Officials Association of Women's Health, Obstetric and Neonatal Nurses Campaign for Tobacco-Free Kids ClearWay Minnesota Community Anti-Drug Coalitions of America Lung Cancer Alliance March of Dimes National African American Tobacco Prevention Network National Association of County & City **Health Officials Oncology Nursing Society** Society for Public Health Education Society for Research on Nicotine and Tobacco Trust for America's Health **Truth Initiative** University of Wisconsin Center for Tobacco Research and Intervention

American School Health Association