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The Honorable Kathleen Sebelius U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW, Room 120F Washington, DC 20201

Dear Secretary Sebelius:

We are writing to ask your Department to clearly define a comprehensive tobacco cessation benefit in the Affordable Care Act regulations or, at the very least, in corresponding guidance documents.

Recently, your Department released the 50th anniversary Surgeon General's report, *The Health Consequences of Smoking – 50 Years of Progress*, which found that smoking is even more hazardous and

takes an even greater toll on the nation's health than previously reported. We appreciate the work that went into producing this historic report and applaud your commitment to reducing tobacco use.

Noting that the "current rate of progress in tobacco control is not fast enough. More needs to be done," the report calls for a number of specific actions, including: "Fulfilling the opportunity of the Affordable Care Act to provide access to barrier-free proven tobacco use cessation treatment including counseling and medication to all smokers". As you noted during the release of the report, and on previous occasions, the Affordable Care Act (ACA) "requires insurance companies to provide tobacco cessation services to their customers." But we are concerned that tobacco users who are ready to quit do not have access to free cessation services under the ACA.

The Surgeon General report notes that the implementation of tobacco cessation treatment coverage mandated by the ACA varies significantly across private health insurance contracts. In fact, evidence indicates that many health plans are not covering services that have been proven to help tobacco users to quit. A 2012 study by Georgetown University's Health Policy Institute found that 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 (i.e., individual, group and phone counseling and both prescription and over-the-counter tobacco cessation medications). Contract language for these plans often contained vague or conflicting language that made it impossible to determine which, if any, tobacco cessation services were covered. When the extent of coverage could be determined, many of these plans excluded coverage of prescription and/or OTC medications for tobacco cessation and excluded certain types of counseling. Also troubling, some of the plans analyzed impose cost-sharing requirements for tobacco cessation treatments.

We believe that this study makes clear that many insurance issuers are not in compliance with the ACA. As a result, many tobacco users' access to tobacco cessation treatment may be limited. This information has been shared with your Department, yet HHS has not taken any action to make clear to insurers what is required under the ACA.

Tobacco cessation treatments have received an 'A' rating by the United States Preventive Services Task Force (USPSTF), which means there is a high certainty that tobacco users will benefit substantially from receiving these services. As an 'A' rated service non-grandfathered group plans and insurance issuers must cover these evidence-based tobacco cessation services with no cost-sharing.

The Interim Final Rule implementing Section 2713 of the PHS Act did not attempt to translate the clinical recommendations of the USPSTF into an insurance coverage benefit. The only description in the Interim Final Rule of the tobacco cessation services that must be covered is the following: "The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products." This statement is only the *summary* of the USPSTF recommendation. The full USPSTF recommendation clearly indicates that counseling and medications are both effective and a combination of counseling and medications "is more effective at increasing cessation rates than either component alone." USPSTF references the United States Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence: A 2008 Update* (the "PHS Guideline"), as the source for a detailed description of effective evidence-based tobacco dependence treatments. Without further guidance from HHS, group plans and health insurance issuers have been able to decide for themselves how to translate the USPSTF clinical recommendation for tobacco cessation services into a covered benefit. Based on the results of the Georgetown University study,

many insurers are interpreting the coverage requirement too narrowly, failing to cover tobacco cessation services that the USPSTF has specifically found to be effective.

We are aware that the implementing regulations for section 2713 of the PHS Act permit issuers to "use reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service to the extent such frequency, method, treatment or setting are not specified in the recommendation or guideline." We do not believe that reasonable medical management should allow plans and issuers to ignore the full USPSTF recommendation that specifically lists both the types of medications and counseling that have proven to be effective. All tobacco cessation services that the USPSTF has found to be effective should be covered, not merely some of them. HHS has been provided evidence that many insurance issuers are ignoring the USPSTF recommendations, and without guidance from the Department, group plans and issuers will continue to not provide tobacco users with the effective set of cessation services that Congress intended.

We strongly recommend that the Department of Health and Human Services, Department of Labor, and Department of the Treasury issue guidance to industry clarifying that "tobacco cessation interventions" include coverage of both counseling sessions and FDA-approved medications and that these interventions will be covered whether or not they are delivered during an office visit. As you know, tobacco users need to be encouraged to use cessation services, and lack of clarity about cessation coverage will result in confusion among both health care providers and consumers, leading to fewer successful quit attempts.

Evidence suggests that providing comprehensive tobacco cessation benefits is cost-effective. In 2006, Massachusetts' Medicaid program (MassHealth) initiated a program to provide tobacco cessation treatments (tobacco cessation medications and counseling) to smokers. A 2012 study published in *PloS One* shows that Massachusetts saved more than \$3 for every \$1 it spent on services to help beneficiaries in the state's Medicaid program quit smoking. These savings are conservative as they do not include long-term savings, savings that may occur outside the Medicaid program, or savings beyond cardiovascular-related hospital admissions. An earlier study found that after Massachusetts implemented this program for all Medicaid beneficiaries, the smoking rate among beneficiaries declined by 26 percent in the first 2.5 years.

There is precedent for HHS to provide guidance beyond the Interim Final Rule on how plans and issuers should comply with the required coverage of USPSTF-recommended services, such as through the FAQs released by the Departments of Labor and Health and Human Services. The failure to clearly define a comprehensive tobacco cessation benefit in regulations or in supplemental information will allow insurers to continue to provide inadequate coverage and impose cost-sharing requirements, contrary to the ACA.

As noted in the recent Surgeon General report, the tobacco cessation benefits contained in the ACA hold great promise but in order to ensure access to cessation services and coverage that reflects the full USPSTF recommendation, we urge you to provide additional guidance on the requirement for coverage of tobacco cessation treatment. With additional guidance, we believe you can make tremendous progress toward accomplishing the specific recommendation laid out in the Surgeon General report and fully maximize the public health benefit of CDC's Tips from Former Smokers media campaign and other HHS efforts to reduce tobacco use.

The following groups stand ready to help in any way in these efforts, which will save lives and money.

Sincerely,

American Academy of Family Physicians

American Academy of Otolaryngology-Head and Neck Surgery

American Association for Cancer Research

American Association for Respiratory Care

American Cancer Society Cancer Action Network

American College of Cardiology

American College of Chest Physicians

American College of Physicians

American College of Preventive Medicine

American Congress of Obstetricians and Gynecologists

American Dental Association

American Heart Association

American Lung Association

American Psychological Association

American Public Health Association

American Society of Clinical Oncology

American Thoracic Society

Association of Maternal and Child Health Programs

Association of State and Territorial Health Officials

Association of Women's Health, Obstetric and Neonatal Nurses

Campaign for Tobacco-Free Kids

Cancer Prevention and Treatment Fund

Legacy

Lung Cancer Alliance

National Association of City and County Health Officials

National Physicians Alliance

North American Quitline Consortium

Oncology Nursing Society

Society for Cardiovascular Angiography and Interventions

Society for Research on Nicotine and Tobacco

cc:

Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services

Gary Cohen, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services