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January 31, 2012

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

Re: Essential Health Benefits Bulletin

Dear Secretary Sebelius:

The American Lung Association appreciates the opportunity to comment on the Essential Health Benefits Bulletin released by the Department of Health and Human Services (HHS) on December 16, 2011. The Affordable Care Act (ACA) and its provisions establishing state health exchanges hold tremendous potential to make our country healthier and to reduce healthcare costs. However, the Lung Association has concerns about how this implementation approach will affect the 45 million American smokers, especially those who want to quit. Following the approach laid out in the bulletin, HHS is missing a crucial opportunity to create a minimum federal standard for tobacco cessation, and instead is likely to create yet another patchwork of inadequate coverage.

***The Importance of Helping Smokers Quit***

Tobacco use is the leading cause of preventable death in this country, responsible for more than 400,000 deaths each year. The Essential Health Benefit sets coverage standards for new Medicaid enrollees and many of the currently uninsured. These two populations (30.5 percent and 32.1 percent respectively) smoke at much higher rates than their privately insured counterparts, aged 18-65 (16.8 percent).[i] Also, new evidence published earlier this month shows that low socio-economic status correlates to more difficulty in quitting smoking.[ii] Not only are the people covered by the Essential Health Benefit more likely to smoke, but this new study shows they are also more likely to have a hard time quitting.

Tobacco use also results in $96 billion annually in healthcare expenditures and an additional $97 billion each year in lost productivity.[iii] Tobacco use is a huge contributor to this nation's growing healthcare costs. But evidence is mounting that there is a tremendous return on investment when smokers are given the help they need to quit. A study was recently released by the George Washington University showing that providing Medicaid enrollees in Massachusetts with help to quit saved the state (and taxpayers) over $3 for every $1 spent on the treatments. These savings were seen in just over a year after the benefit was in place and do not take into account the long term savings that would be realized

with fewer cases of lung cancer, COPD and heart diseases.[iv] These savings are not only real, but they accrue in a very short time period.

Over 70 percent of smokers want to quit – but most smokers require multiple attempts before they are successful because the addiction to tobacco is incredibly powerful. Treatment for tobacco cessation is not one-size-fits-all. Just like other medical conditions, individuals respond to treatment differently. It is normal for patients to try more than one treatment before finding the right one. For all these reasons, it is important that cessation benefits offered to tobacco users are **comprehensive** – which means based on the most recent U.S. Public Health Service guideline, *Treating Tobacco Use and Dependence.*

***Tobacco Cessation and Insurance Coverage***

To save lives and scarce funds, all tobacco users in the U.S. must have access to a comprehensive tobacco cessation benefit. The federal government can play a large role in accomplishing this goal. In 2011, the federal government became a model for this type of coverage when the U.S. Office of Personnel Management began requiring insurance plans that participated in the Federal Employees Health Benefits Program (FEHB) to cover:

- Four tobacco cessation counseling sessions of at least 30 minutes for at least two quit attempts per year. This includes proactive telephone counseling, group counseling and individual counseling.
- All seven Food and Drug Administration (FDA)-approved tobacco cessation medications.[v]
- Two quit attempts per year.
- These benefits must be provided with no copayments or coinsurance and not subject to deductibles, annual or life time dollar limits.

Federal employees and their dependents now have access to a model tobacco cessation benefit. **The American Lung Association urges the federal government to enact requirements and policies that provide this tobacco cessation coverage to other populations – particularly low income and/or needy populations like Medicaid and people buying insurance through state exchanges.**

Experience has shown that leaving this up to states or to individual health plans results in confusing and inadequate coverage. According to primary data collected by the American Lung Association and available at www.lung.org/cessationcoverage, only six states provide a comprehensive cessation benefit to all Medicaid enrollees.[vi] Only five states provide comprehensive coverage through state employee health plans.[vii][viii] For consumers and employers that buy private health insurance, coverage varies greatly. The Essential Health Benefits Bulletin recognizes this fact, stating that smoking cessation programs and medications are "not all consistently covered by small employer health plans." One study in Colorado found similar results – that while some preventive services are covered similarly from plan to plan, tobacco cessation is not.[ix]

**In the absence of a federal standard, coverage that states or insurance plans implement is far short of comprehensive, and Americans are missing out on the potential savings in lives and money.**

The approach laid out in the December 16 bulletin misses an historic opportunity to create a minimum federal standard for tobacco cessation –which would save lives and money. This patchwork approach will create more confusion and will not guarantee anyone coverage for the treatments they need. However, despite our preference for a comprehensive nationwide approach, the American Lung

Association makes the following recommendations in response to the bulletin to ensure robust preventive services coverage:

***HHS Should Require State Plans to Cover All 'A' and 'B' Rated Preventive Services***

The Affordable Care Act puts an appropriate and necessary emphasis on prevention in the U.S. healthcare system. Not only will focusing on preventing disease make Americans happier and healthier, but it will also save money. One of the ways the ACA emphasizes prevention is by requiring all new private health plans to cover all preventive services given an 'A' or 'B' rating from the U.S. Preventive Services Task Force (USPSTF) with no cost sharing. These 'A' and 'B' services are evidence based, provide strong value, help patients take control of their health and will improve the health of the population. That is why, consistent with Congress's intent, the ACA makes them part of a baseline of coverage, and why they should be provided to all Americans.

This focus on prevention was extended to state exchanges in the ACA. As you well know, preventive services are one of the ten coverage areas required to be present in the Essential Health Benefit. **We urge HHS to issue regulations requiring state plans to include coverage of all 'A' and 'B' services as the way to fulfill the preventive services requirement for benchmark plans.** This would be consistent with other parts of the ACA law, and ensure that the requirement for non-grandfathered private plans is not undermined. It would also move towards a national standard in preventive services coverage, and would ensure that the Essential Health Benefit includes benefits in a "typical employer plan," as the ACA requires.

Tobacco cessation treatment is one of the services that receive an 'A' rating from the USPSTF. Unfortunately, the 'A' rating does not provide detailed guidance on how to translate this into insurance coverage. In addition to requiring coverage of 'A' and 'B' rated services, the American Lung Association also urges HHS to issue further guidance on what specific treatments are required to be covered for tobacco cessation. HHS should follow the Office of Personnel Management's example in this guidance and require a comprehensive tobacco cessation benefit. This would not only guarantee smokers in state exchanges access to a comprehensive benefit, but the requirement would also reach smokers in non-grandfathered, private insurance plans.

***2016 Re-Evaluation Will Require Comprehensive and Publicly Available Tracking***

The Essential Health Benefits Bulletin states that this implementation approach will be re-evaluated in 2016. In order to truly evaluate this policy, steps must be taken now to ensure policymakers and other interested parties have all the information that is needed to determine whether HHS's current proposal results in states adequately helping their smokers quit.

**HHS must track in detail what coverage is actually offered to patients in exchanges.** It must set up a process now to collect this information. Unfortunately, the Department of Labor (DOL) methodology is insufficient to ascertain whether states are helping smokers quit. The report that DOL prepared for HHS in preparation for the implementation of Essential Health Benefits was not detailed enough to address all specific areas of coverage. Specifically, this was a survey of Summary Plan Documents. These documents provide an inadequate summary and do not include specific listings of all treatments covered.

If HHS or DOL plans to collect this information via Summary Plan Documents again, it must require plans to include a more comprehensive report of covered benefits. For instance, many summary plan documents simply reference coverage of "preventive services." HHS must require a report that details

the specific services that are covered. If HHS or DOL uses a different method of collecting and tracking information on coverage in the exchanges, we encourage a more comprehensive approach to data collection.

The American Lung Association is particularly concerned about tobacco cessation treatment. To adequately evaluate whether plans in the exchanges are providing Americans with enough help to quit smoking, **HHS must track whether plans cover all seven FDA-approved medications for tobacco cessation plus individual, group and phone counseling.** As people in exchanges are particularly cost-sensitive, HHS must also track whether plans require cost-sharing for these treatments. The Lung Association urges HHS to make this tracking information available publically so that there can be a full and complete evaluation in 2016.

***Increase Patient Protections in Required Pharmacy Benefits***

The American Lung Association has decades of experience in directly helping smokers quit, and know that it is important for smokers and their healthcare providers to be able to choose the treatment that is right for them. There is not one smoking cessation medication that will work for everyone, and doctors and patients need to have multiple options when making treatment decisions. This is why it is so important to implement the pharmacy provisions of the Essential Health Benefit with the patient first in mind.

The Lung Association was surprised that HHS proposed to only require plans to cover one medication per every drug class on the benchmark plan's formulary. **At a minimum, the Lung Association recommends that this requirement be made consistent with Medicare Part D coverage -- two drugs per class.** Specific to helping smokers quit, HHS should require all FDA approved drugs be covered in the smoking cessation drug class.

The Essential Health Benefits Bulletin does not address coverage of over-the-counter (OTC) drugs in the exchanges. HHS must address this topic, as many plans presently cover some of these medications. Sometimes plans list OTC medications on their formularies, but sometimes this coverage is detailed on a separate list of covered over-the-counter drugs. Furthermore, in the case of tobacco cessation, OTC medications might be covered through a smoking cessation program (like a phone quitline), and they are not on the formulary or OTC list. If a benchmark plan covers OTC medications, but does not include them on its formulary, would plans in the exchange be required to cover those OTC medications? **HHS must address this question as well as require appropriate OTC coverage.**

If HHS takes an approach similar to Medicare Part D with pharmacy coverage, it **must require plans to use a standard drug category and class system.** HHS should choose a system that includes a classification for smoking/tobacco cessation medications. Currently, experience has shown that plans sometimes list tobacco cessation medications under a "Miscellaneous" category. Allowing plans to have that category would be counterproductive and subvert the whole system of requirements and evaluation.

***HHS Should Make Information on Benchmark Plan Options Publicly Available***

In order to make informed decisions on which plan to choose as a benchmark, states must collect a lot of information on plans in a short amount of time. **The American Lung Association urges HHS to help states in this process by publishing on its website which plans are options for benchmark status, and providing detailed and comprehensive information on each plans' coverage.** The information must

include a full list of covered services and medications. This information must be provided to state policymakers and the public as soon as possible.

**Broader Implementation Questions**

Lastly, the Lung Association has several questions about the implementation process that impact tobacco cessation and more broadly, benchmark plans in general. The Lung Association urges HHS to address them in future regulations. These questions include:

1. Please clarify the definition of a "plan" that is potentially eligible to be a benchmark option.
2. How long will benchmark designation last? Will states be expected to re-evaluate benchmarks every year? Every two years?
3. What happens when a benchmark plan's coverage changes? Do benchmark requirements for other plans change with it, or stay the same as when the benchmark was chosen?
4. How will a state's benchmark requirements interact with the federal exchange (which according to ACA will be created for states that do not establish their own exchange in time)?
5. Will the exchange benchmark also be the benchmark for newly eligible Medicaid enrollees, or will that be yet another separate benchmark?

Thank you for the opportunity to comment on this important matter. The American Lung Association welcomes the opportunity to work with HHS on the implementation of the state health exchanges.

Sincerely,

Charles D. Connor
President and CEO

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[i] Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey Raw Data, 2010. Analysis performed by the American Lung Association Research and Program Services Division using SPSS and SUDAAN software.

[ii] Sheffer CE, Sitzer M, Landes R, Brackman L, Munn T, Moore P (2012) Socioeconomic Disparities in Community-Based Treatment of Tobacco Dependence. American Journal of Public Health. e-View Ahead of Print. doi: 10.2105/AJPH.2011.300519

[iii] Centers for Disease Control and Prevention. Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000-2004. *Morbidity and Mortality Weekly Report.* November 14, 2008; 57(45): 1226-28.

[iv] Richard P, West K, Ku L (2012) The Return on Investment of a Medicaid Tobacco Cessation Program in Massachusetts. PLoS ONE 7(1): e29665. doi:10.1371/journal.pone.0029665. Available at: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0029665

[v] The benefit should refer to "all FDA-approved medications" and not specify a number in order to ensure that future FDA approved therapies can be included most easily.

[vi] As of January 17, 2012, these states are Indiana, Massachusetts, Minnesota, Nevada, North Carolina and Pennsylvania.

[vii] As of January 17, 2012, these states are Illinois, Indiana, Maine, New Mexico and North Dakota.

[viii] American Lung Association. "Helping Smokers Quit: Tobacco Cessation Coverage." December 2011. Available at www.lung.org/helpingsmokersquit

[ix] Centers for Disease Control and Prevention. Health Plan Implementation of U.S. Preventive Services Task Force A and B Recommendations—Colorado, 2010. MMWR 2011;60(39):1348-1350. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6039a3.htm?s_cid=mm6039a3_x