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December 26, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-9972-P

Dear Secretary Sebelius:

The American Lung Association appreciates the opportunity to submit comments regarding CMS-9972-P, the proposed rule on the Patient Protection and Affordable Care Act, Health Insurance Market Rules and Rate Review. The Lung Association is particularly concerned with the provisions of the rule implementing the tobacco rating, and how this implementation will affect tobacco users – especially tobacco users who are trying to quit or may try in the future.

Opposition to Tobacco Surcharge

The American Lung Association opposed section 2701 of the Affordable Care Act (ACA), which allows insurance plans in the individual and small group markets to charge tobacco users up to 50 percent more in premiums than non-tobacco users. This policy will herein be referred to as the "tobacco surcharge."

A health insurance surcharge for tobacco use and what is for many, a chronic disease of tobacco addiction, is likely to produce adverse consequences. There is little evidence that financial incentives or disincentives through insurance premiums change individual behavior. Tobacco surcharges are an unproven theory to improve public health – in contrast to several thoroughly tested, evidence-based interventions and policies that *are* proven to reduce smoking consumption and prevalence. These tools include higher tobacco taxes on all tobacco products, smokefree air laws and cessation and prevention programs including advertising. From the experience of states like California and Massachusetts and cities like New York, it is clear that comprehensive tobacco control polices can reduce smoking rates by 23 percent or more over just a few years.[1]

More importantly, higher health insurance premiums due to the tobacco surcharge will create a barrier for individuals who need coverage the most, likely resulting in more people paying the penalty instead of buying insurance. A recent analysis by Rick Curtis and Ed Neuschler of the tobacco rating impact on California consumers confirms this unintended result.

*"Smokers with lower incomes who are eligible for premium tax credits would generally face **prohibitively high health insurance premiums** under the maximum 50 percent tobacco-rating factor allowed by the ACA."*[2] [emphasis added]

In their example, an average adult who identifies as a tobacco user could have a premium of $5,200 for an exchange benchmark plan with the surcharge, representing 18.7 percent of his or her income and well above the 8 percent of income considered affordable under the ACA. Not only do the tobacco surcharges increase the price of health insurance, this policy will result in greater numbers of uninsured than would exist without a tobacco rating. In California, between 200,000 and 400,000 people would remain uninsured if the 1.5 rating is implemented.[3] This consequence goes directly against the purposes of the ACA: to provide access to quality, affordable health insurance to a greater population.

There are additional concerns about the specific populations that would likely be priced out of affordable health insurance. Tobacco users, particularly smokers, are disproportionately in a racial minority, low-income and less educated. Native Americans have a smoking prevalence about 33 percent and African American smoking prevalence is above 20 percent.[4] Thirty-four percent of the nearly poor and 31.4 percent of the middle income population smoke in the U.S. while only 20 percent of those with higher incomes are current smokers.[5] Across all racial groups, those who are classified as nearly poor or middle income have higher smoking rates than those of higher income.[6] Tobacco related-diseases like cancer, lung and heart disease disproportionately impact these populations, who are less likely to get adequate medical services and are more likely to die of these tobacco-related conditions than higher income or non-racial minority individuals. For example; for lung, colorectal and prostate cancers combined, death rates among African American and white men with 12 or fewer years of education are more than twice those of men with higher levels of education.[7]

The American Lung Association recognizes that section 2701 of the ACA is law. However, the Lung Association urges HHS to consider these points when implementing the provision, and to minimize the adverse impacts mentioned. To that end, the American Lung Association makes several recommendations to follow.

Identification of Tobacco Users

Tobacco dependence is best measured in a clinical setting using proven, established protocols for assessing tobacco dependence. Unfortunately, these measures are meant to be used by health professionals when evaluating patient health and needs, not by the general public unaccompanied by any professional guidance.

Some insurers that charge tobacco surcharges use testing to assess tobacco use, such as blood or saliva tests that measure cotinine levels as a marker of tobacco use. The Lung Association believes that these tests should not be used by insurance companies or employers to identify tobacco users because of problems with accuracy and impact on those trying to quit tobacco use. Relying on cotinine markers may produce false positive results for people heavily exposed to secondhand smoke at work or home and for those currently using nicotine replacement therapy. These tests would likely prove overly burdensome and costly for the employer, insurer and for the consumer, especially if regular testing or verification would be required.

In the proposed rule, HHS recognizes that most issuers that charge tobacco surcharges employ self-attestation to determine tobacco use status. While this self-reporting could produce inaccuracies as well, the Lung Association believes this is the better method for determining tobacco use status.

Recommendations

- Tobacco users eligible for the tobacco surcharge should be identified by self-reporting whether or not they currently use tobacco products.
- Methods for identifying tobacco users should be applied consistently across consumers to avoid any possibility of discrimination on the basis of age, geographic location, race or ethnicity, income or other demographic characteristic.
- The insurer should be required to make clear to the tobacco user in the self-reporting document that the user cannot be charged a premium if they are enrolled in a cessation program.
- If a person becomes a new user during the year (i.e., they accurately said they were not at the time of enrollment), they should be allowed to enter a cessation program without charge for the service and without being charged a tobacco surcharge.
- If a person self-attests as a tobacco user but initially refuses to enter a cessation program, they are subject to the surcharge. If, however, during the year the user changes his or her mind and enters a cessation program, the surcharge should stop at that point. HHS should establish a process to ensure that this can occur.
- HHS should clarify that a misstatement regarding tobacco use, or enrollment in a plan's cessation program, is not grounds for rescission. The department should further clarify that if there has been a misrepresentation, intentionally or unintentionally, the insurer can only collect the surcharge that should have been paid for one year.
- Consistent with other ratings factors measurement, tobacco use should only be measured once a year at the time of enrollment or re-enrollment.
- In light of the significant economic consequences associated with being a tobacco user, HHS must work to minimize the incentive a tobacco user would have to not answer this question truthfully.

Definition of Tobacco Use

As noted in the proposed rule, no uniform, widely-used definition of tobacco use exists among states for either rating purposes or even in the context of some tobacco control laws. While there are clear clinical definitions of tobacco dependence used by HHS, many federal, state and local public health agencies, as well as the medical community, these medical-based definitions are not appropriate for rating purposes. Consumers enrolling in insurance plans are unlikely to understand the nuances of clinical tobacco dependence definitions and terminology that are required for an accurate assessment of their tobacco use status.

Definition of Tobacco Products

The extensive number and breadth of tobacco products being introduced by the tobacco industry each year (e.g., dissolvable tobacco products, tobacco strips and various types of electronic "cigarettes") creates significant complications in creating a consistent and workable definition of tobacco use. Some definitions of tobacco and tobacco use include a catch all phrase such as "other tobacco products" intended to cover emerging and future products derived from the tobacco plant that may not yet be on the market for consumers. Including this type of open-ended definition has the benefit of automatically including new and not-yet-known tobacco products as they are introduced without needing to go through any updating of plans, regulations, or guidance. In the context of insurance rating, however, attempting to include all existing and emerging tobacco products while leaving room for any another product that may be also used by the consumer is cumbersome and confusing to the insurer and the consumer.

The Food and Drug Administration (FDA) has stated that it considers a wide variety of products to be tobacco products, including cigarettes, cigars, cigarillos, smokeless tobacco, snus, dissolvable tobacco and e-cigarettes with nicotine derived from tobacco. At this time, however, FDA's tobacco regulations apply only to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, with the opportunity to extend authority to any other tobacco products deemed to fit the definition. The FDA has stated its intent to extend its authorities under the Food, Drug and Cosmetic Act, to other categories of tobacco products that meet the statutory definition of "tobacco product", but has not done so and therefore does not use one, simple, perpetual term for identifying what is and what is not a tobacco product or tobacco user.[8] The general public may have difficulty determining what the agency with regulatory authority over tobacco even considers a tobacco product.

A 2012 CDC study highlights problems associated with the questions used to ask whether someone uses a tobacco product, specifically cigar use.[9] Youth respondents were asked if they used cigars and similar products, and then were asked a follow-up question as to whether they smoked Black & Milds. The study found that more than half (57%) of Black & Mild users said they did not smoke cigars. While this particular study focused on youth tobacco reporting, the point made by the researchers that "Differences in content knowledge and everyday colloquial expressions may be responsible for misreporting of cigar use" is relevant here.

Definition of "use"

In addition to the types of tobacco products covered, frequency of tobacco use and the time period covered are important components to defining tobacco use. Is a tobacco user someone who smokes every day, most days, or some days? How many cigars a week or a month are considered tobacco use? How many dips of smokeless tobacco per day or week would qualify? What about e-cigarette or hookah use? Does the tobacco use have to occur in the last thirty days, last year, or in a lifetime? Would the definition cover occasional/light smokers, current smokers, or ever smokers, as defined by the Institute of Medicine and used in many national and state tobacco use surveys?[10]

Any definition of tobacco use must take into account the evidence that tobacco users may have different perceptions of their status then insurers or public health authorities. The questions regarding tobacco use must minimize the potential for a consumer to be exposed to accusations of fraud or false reporting. Studies show that some smokers do not report to be smokers, raising the risk of not understanding enrollment questions about tobacco use status. For example, in studies of college students, over half of students who reported smoking a cigarette in the last 30 days responded "no" to a the question of whether they are a smoker.[11,12] Smoking trends are also pointing to fewer daily smokers, which may affect how smokers are identified or identify themselves.[13] Even among "occasional" smokers, large differences exist in smoking history, smoking patterns, and perceived addiction.[14]

Additionally, users of newer or less common tobacco products may not consider themselves tobacco users because they are not using cigarettes or traditional smokeless tobacco. An occasional, or even regular, user of an e-cigarette, tobacco orbs, or flavored cigarillos does not necessarily identify as a smoker or tobacco user because they are not smoking cigarettes and they do not consider themselves addicted to tobacco.

Recommendations

- The general definition of tobacco use should be based on the tobacco products FDA has the authority to regulate with a standard look-back period, but be refined for the purposes of insurance applications. FDA's tobacco regulations currently apply only to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, with the opportunity to extend authority to any other tobacco products deemed to fit the definition. These products include cigars, cigarillos, snus, dissolvable tobacco, e-cigarettes or any other product with nicotine that is derived from tobacco.
- While there is variation in what frequency of using tobacco makes someone a "tobacco user", CDC and the Institute of Medicine use a 30-day time frame to define a current user, which is a reasonable period that could be used in an insurance application and reasonably understood by the consumer. The Lung Association recommends the use of the 30-day time frame.
- The definition should also include a measure of how often someone uses tobacco within that 30-day period. The World Health Organization (WHO) considers someone a "regular" tobacco user if they use at least one tobacco product a day, while other survey instruments ask respondents if they smoke or use tobacco every day, some days, or not at all.
- Because self-attestation protocols for tobacco use appear to differ widely among states and plans today, the precise questions and format for tobacco use status that would produce the best and most accurate results are not clear. HHS should use its planned consumer testing program to test various language, questions, and definitions of tobacco. After evaluating the results, HHS should apply nationally whichever protocol produces the most accurate, reliable and consistent measure of actual tobacco use.

Consumer Testing

HHS must work with experts in communicating with consumers to create these questions. HHS should test various levels of detail in the definition from a fairly narrow definition of tobacco use to a definition that encompasses a broader range of tobacco products and frequency of use. The testing should seek to measure the accuracy and consistency of responses. Examples of possible questions for testing include:

- Have you smoked cigarettes or cigars or used smokeless tobacco every day in the last 30 days?
- Have you smoked cigarettes or cigars or used smokeless tobacco at any time in the last 30 days?
- Have you used at least one of these tobacco products every day in the last 30 days: cigarettes, cigars, cigarillos pipe, smokeless tobacco, snus, or dissolvable tobacco tablets?
- Have you used any of these tobacco products at any time in the last 30 days: cigarettes, cigars, cigarillos pipe, smokeless tobacco, snus, dissolvable tobacco tablets, e-cigarettes or any other product containing tobacco?

If a list of products is included, insurers should be required to update the products yearly to include all products under FDA's regulatory authority.

<u>Tobacco Surcharge Application</u>

Consumers must have full and clear information about the premium surcharge, what they must do if they wish to avoid paying the surcharge, and the cessation services available through the insurance plan. The information must be simple, in consumer-understandable language, and not require excessive time or burden on part of the consumer. Without this information, it is very likely that consumers might misunderstand how and why the rating is applied, how it impacts their premiums, or the cessation options.

The tobacco rating factor should not be applied to people under 18 covered by the insurance policy. Adolescent tobacco use initiation, patterns of use, and cessation treatments are substantially different than those of adults. Children are not going to be responsible for paying the premium surcharge, thus are not directly impacted by the implied financial incentive to quit. Furthermore, accurate and complete assessments of tobacco use by dependents under 18 are likely difficult. Adolescents cannot be relied on to provide parents or other adult family members with honest assessments of the products they use or the frequency of use, due to family dynamics and other personal situations. The high premium surcharge may even discourage youth from revealing tobacco use, thus raising the likelihood that they will not get needed help to quit. Discussion of tobacco use are best left up to the family and the family's health care professionals, not an insurance application with potentially very large legal and financial implications. If this cannot be done under federal law, we encourage HHS to clarify that states have the option to limit tobacco rating to adults.

Recommendations

- Require that consumers be provided the opportunity to state that they wish to enroll or intend to enroll in a cessation program during the insurance purchasing process, whether online, over the phone, or other means.
- An indication by the tobacco user purchasing insurance that he or she intends to enroll in a cessation program should be sufficient to avoid paying the tobacco surcharge. Limiting the types of cessation programs, requiring completion of certain treatments, or tracking use of cessation services can discourage successful quit attempts. Tobacco users may not be able to quit successfully while in treatment and should be able to schedule their quit attempts and what treatments they will use according to what will give them the greatest chance of success, not the insurance company's requirements. Tobacco addiction is a chronic disease that takes most smokers at least 4-6 quit attempts over multiple years to successfully quit.[15]
- Require that insurers post a clear disclaimer with the premium information, in consumer-friendly language, which states that failure to indicate intention to enroll in a cessation program will result in higher premiums.
- Any requirements for consumers to show cessation enrollment or intent to enroll in cessation should not be more frequent than once a year.
- The regulation and any subsequent guidance should emphasize that states have the freedom to limit tobacco use ratings to a lower ratio than 1.5:1, or prohibit tobacco surcharges entirely. HHS should specifically enumerate the implications of the high, lower, and no rating so that state plans are provided clear information about the implications of the tobacco rating, including its impact on access to insurance for lower-income populations.
- Specify that the tobacco use rating applies to only those beneficiaries age 18 and older.

Cessation Services

It is imperative that evidence-based cessation services must be offered and be free of charge to the consumer in both the small group and individual markets if the consumer is subject to the tobacco surcharge. Including cessation treatments as a covered health benefit increases quit rates by 30 percent.[16]

While the ACA provides that cessation services must be offered in new plans in the small group and individual markets, a recent review of implementation of this provision in several states for the Campaign for Tobacco-Free Kids shows that plans are not following the law. In an analysis of individual market, small group market, state employee, and federal employee plan contracts, researchers found

extensive discrepancies with implementation and wide variation among the plans claiming to offer cessation benefits.[17] The analysis found that 26 of the 39 contracts excluded some or all tobacco cessation services despite other provisions indicating that coverage is provided. Seven of the contracts required cost-sharing for tobacco services, including counseling and prescription cessation drugs, in direct conflict with ACA requirements that USPSTF graded 'A' preventive services be offered without cost-sharing. Many of the plans contained barriers to access to cessation treatment, such as medical necessity requirements pre-existing condition exclusions, specific program requirements, and even health risk assessments. Cost sharing, even when minimal, and these types of administrative barriers are shown to decrease access to cessation services and impede reduction of tobacco use rates.

Recommendations

- HHS must release clear guidance on what tobacco cessation treatments plans are required to cover without cost-sharing through preventive services benefits.
- This guidance should specify that coverage of all medications FDA-approved for tobacco cessation and all types of counseling recommended by the Public Health Service Guideline on *Treating Tobacco Use and Dependence*[18] must be covered.
- Plans should be required to institute coverage of tobacco cessation treatments at least 6 months in advance of the tobacco surcharge taking effect. This way tobacco users are given an opportunity to quit before the premium will affect them.

Coordination with Wellness Programs

HHS proposes to coordinate implementation of the tobacco surcharge with employer wellness programs, citing administrative efficiency and encouragement of the use of tobacco cessation services offered in the program. The Lung Association commends the Department's efforts to extend cessation services to a broader population through insurance plans, but does not fully support the proposal to directly link the two provisions. Successfully quitting tobacco use is a unique and complex process for millions of people and tobacco addiction is a chronic condition not easily remedied. Cessation requires comprehensive and tailored treatment options and services that are easily and readily accessible to any tobacco user who wants to quit, including phone counseling, individual and group counseling by addiction experts, medications, and over the counter therapies.

A general employer wellness program may contain some cessation services, but as the detailed features are not set out in regulation or guidance, it is very likely that some or even many tobacco users will not have access to adequate cessation resources. In order to avoid the tobacco surcharge, tobacco users should not be required to enroll in a general wellness program that deals with a variety of lifestyle behavior and health issues. Tobacco users may benefit from weight management, nutrition and other services within the wellness program. What they require, however, is focused, high-quality, evidenced based cessation treatment as recommended by the U.S. Public Health Service[19] and the CDC. The enrollee should be free to find an appropriate cessation program in their community and not be limited to the one offered through an employee wellness program.

On the issue of potential conflict between sections 2705(b) and 2705(j) noted in the proposed regulation, the Lung Association recommends that small employer plans that do not offer a wellness program and that choose to apply a tobacco use rating be required to fully reimburse employees for tobacco cessation treatments. Without such a requirement, tobacco users would face significant financial burden without sufficient resources to quit that is necessary to avoid the surcharge. Very few tobacco users can quit without quality cessation resources, so the absence of these services directly conflicts with the public health goal of the ACA of decreasing tobacco use. Offering adequate cessation

services, as documented by the U.S. Public Health Service and in dozens of studies, increases successful quit rates by up to 30 percent.[20] Successful quitting should be the ultimate goal of implementation of these provisions.

Recommendation

- The ability of a tobacco user to forego the surcharge should not be directly linked to participation in a cessation program offered through a wellness program. The enrollee should be allowed to use a cessation program offered through an employer or insurer's wellness program, but the enrollee should also have the option of participating in any evidence-based cessation program that they choose, both in the individual or small group market.

Data Collection

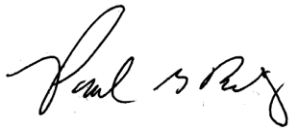
HHS must require plans to enhance data collection for tobacco users' utilization of cessation programs as insurers implement the tobacco premium. The American Lung Association urges that insurers be required to collect data at the participant level and regularly submit it to HHS regarding:

- Tobacco-use prevalence.
- Rates of coverage among users.
- Number of quit attempts.
- Utilization of cessation counseling and FDA-approved medications.
- Number of people who successfully quit.

These data will allow HHS to analyze the actual results and implementation of the premium so that it can revise or update policies based on implementation.

Thank you for consideration of our comments.

Sincerely,



Paul G. Billings
Senior Vice President, Advocacy and Education

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