



September 17, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIO-9992-IFC
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Baltimore, MD 21244-1850

To Whom It May Concern:

We are writing in response to the Interim Final Rules for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act, which were published in the Federal Register on July 19, 2010.

The Interim Final Rules identify the preventive services that group health plans and health insurance issuers (other than grandfathered plans) will be required to cover and how the prohibition of cost-sharing requirements on these preventive services is to be applied. The rule specifies that group plans and insurance issuers will be required to cover preventive services that have received an A or B rating from the U.S. Preventive Services Task Force (USPSTF), including tobacco cessation interventions.

The Interim Final Rules, however, do not provide any specificity about the scope of the tobacco cessation services that are to be covered. We strongly encourage the Secretary to issue guidance to group plans and insurance issuers to clarify that the tobacco cessation coverage requirement covers all forms of counseling and FDA-approved medications and is not limited to counseling and interventions delivered during an office visit.

For many covered preventive services, the description of the USPSTF recommendation in the Interim Final Rules provides sufficient information for group plans and insurance issuers to translate this clinical recommendation into a covered insurance benefit. But for other preventive services, the brief description of the USPSTF recommendation in the rule creates a possibility that group plans and insurance issuers will define the USPSTF recommendation too narrowly. The lack of specificity in defining the USPSTF recommendation is especially problematic given the Interim Final Rules provision permitting plans and issuers to use "reasonable medical management techniques" to establish any coverage limitations if the USPSTF recommendation "does not specify the frequency, method, treatment, or setting for the provision of that service."

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 the summary of the USPSTF recommendation. The full recommendation, which can be found on the Agency for Healthcare Research and Quality website (www.ahrq.gov/clinic/uspstf09/tobacco/tobaccors2.htm), more clearly defines the scope of the

service. The USPSTF recommends both counseling and medications as effective interventions for tobacco cessation. The USPSTF states:

- counseling can be delivered effectively by “various primary care clinicians”;
- there “is a dose-response relationship between quit rates and the intensity of counseling” and quit rates appearing to “plateau after 90 minutes of total counseling contact time”;
- telephone quitlines improve cessation rates;
- FDA-approved pharmacotherapies that are effective for treating tobacco dependence in nonpregnant adults include “several forms of nicotine replacement therapy (gum, lozenge, transdermal patch, inhaler, and nasal spray), sustained-release bupropion, and varenicline”; and
- a combination of counseling and medications “is more effective at increasing cessation rates than either component alone.”

The USPSTF recommendation also references the U.S. Public Health Service Clinical Practice Guideline “Treating Tobacco Use and Dependence: 2008 Update” (www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf), which provides more detailed reviews and recommendations on tobacco cessation services. The PHS Guideline states:

- “proactive telephone counseling, group counseling, and individual counseling formats are effective and should be used in smoking cessation intervention;”
- “intensive counseling is especially effective” and “when possible, the intensity of the program should be” four or more sessions that are each longer than 10 minutes;
- all seven FDA-approved cessation pharmacotherapies – gum, patch, lozenge, nasal spray, inhaler, bupropion, and varenicline – are effective in helping people quit, including over-the-counter and prescription-only medications; and
- “tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit.”

We believe the Interim Final Rules’ lack of specificity in defining the tobacco cessation services creates a risk that consumers will not have access to the full array of services that have proven to be effective. We strongly recommend that the Department of Health and Human Services, Department of Labor, and Department of the Treasury issue guidance to industry that clarifies 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. We also recommend that group plans and insurance issuers attest to the Departments that the tobacco cessation benefit they are providing does not conflict with the full USPSTF recommendation or the PHS Guideline.

Coverage of comprehensive tobacco cessation services will greatly enhance tobacco users’ access to life-saving treatments. Helping more people quit will improve health, save lives, and help restrain health care costs. We greatly appreciate your leadership on this issue and your consideration of our recommendations.

Sincerely,




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