



Arnold Schwarzenegger, Governor  
State of California  
Business, Transportation and Housing Agency

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September 16, 2010

**VIA: Regulations.gov Portal**

Mr. Jay Angoff  
Director  
Office of Consumer Information and Insurance Oversight  
U.S. Department of Health and Human Services  
Attention: OCIO-9992-IFC  
P.O. Box 8016  
Baltimore, MD 21244-1850

**RE: INTERIM FINAL RULES RELATING TO COVERAGE OF PREVENTIVE SERVICES UNDER SECTION 2713 OF THE PUBLIC HEALTH SERVICE ACT (File Code: OCIO-9992-IFC)**

Dear Mr. Angoff:

The California Department of Managed Health Care ("DMHC") appreciates the opportunity to comment on the Interim Final Rules<sup>1</sup> ("the Rules") issued under Public Health Service Act Section 2713 (regarding coverage of certain preventive care items and services with no cost sharing) ("Section 2713"), as added or amended by the Patient Protection and Affordable Care Act of 2010 ("ACA").<sup>2</sup>

The DMHC is the California agency that licenses and regulates health care service plans ("health plans") under the Knox-Keene Health Care Service Plan Act of 1975 ("Knox-Keene Act").<sup>3</sup> There are 111 health plans providing managed health care services to 21 million Californians and operating under this state licensing law. California's regulation of health care coverage is divided between the DMHC, which regulates all managed care plans, including some preferred provider organizations ("PPOs") issued by health plans, and the Department of Insurance, which regulates indemnity carriers that issue health insurance policies, including PPOs.

The DMHC applauds the focus on preventive health care policies and programs in the ACA. The individual and societal health benefits and cost-savings from utilizing the preventive services described under Section 2713 are many and will result in increased utilization, particularly among the population that cannot now afford such interventions.

The relationship of Section 2713 to the standards enumerated by the United States Preventive Services Task Force ("USPSTF"), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the Health Resources and Services

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<sup>1</sup> 75 FR 27138 (July 19, 2010).

<sup>2</sup> Public Law 111-148 (Mar. 23, 2010) 124 Stat. 119.

<sup>3</sup> California Health and Safety Code Section 1340, et seq.

Administration, is helpful and instructive to the DMHC regarding health plans' coverage responsibilities. However, there are several items and services listed under the USPSTF recommendations for which greater clarification is necessary for all stakeholders to understand their rights and responsibilities.

## I. TOBACCO USE

For example, the USPSTF lists "Counseling and Interventions to Prevent Tobacco Use Tobacco-Caused Disease in Adults and Pregnant Women" as an "A" rated recommendation. Specifically, the recommendation calls for clinicians to "ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products" and, with respect to pregnant women, "ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke."

The USPSTF's Guide to Clinical Preventive Services ("the Guide") states that, "brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates... Effective interventions may be delivered by a variety of primary care clinicians." The Guide also discusses the efficacy of the 5-A behavioral counseling framework,<sup>4</sup> various aspects of patient-specific counseling, and other complementary common practices, including motivational interviewing, intensive counseling, referrals, telephone "quit lines," and clinical screening systems designed to regularly identify and document patient's tobacco use. The Guide also discusses the prescribing of FDA-approved pharmacotherapy that has been identified as safe and effective for treating tobacco dependence, including nicotine replacement therapy (including nicotine gum, nicotine lozenges, nicotine inhalers, nicotine transdermal patches, and nicotine nasal spray) and sustained-release bupropion, clonidine, and nortriptyline, among other medications.

Unfortunately, the information provided by the USPSTF with respect to tobacco cessation does not delineate specifically enough which services and items must be provided without cost sharing. For instance, if a patient presents as a tobacco user, is the clinician's responsibility under the Guide to ask about tobacco use, or is it to ask about tobacco use, counsel against such use, and, if appropriate, refer to other clinicians and/or prescribe medication? Which of these services and items is a health plan required to cover without cost sharing? If a tobacco-using patient is referred to counseling and prescribed a medication to assist in their tobacco-cessation efforts, may a health plan impose cost sharing on those counseling sessions and require a prescription co-pay? Are all smoking cessation prescription drugs to be covered without cost sharing or only some? Must a health plan pay for all over-the-counter smoking cessation aids, some, or none? These types of questions illustrate the need for further guidance.

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<sup>4</sup> The 5-A behavioral counseling framework provides a useful strategy for engaging patients in smoking cessation discussions: 1. Ask about tobacco use. 2. Advise to quit through clear personalized messages. 3. Assess willingness to quit. 4. Assist to quit. and 5. Arrange follow-up and support.

## II. MEDICAL MANAGEMENT

While the Rules do allow for health plans to utilize “reasonable medical management,” the parameters of this management are unclear. For example, studies have shown that many smokers cannot successfully quit on their first and even subsequent attempts. If health plans provide coverage for smoking cessation items and services, must they provide them indefinitely until a smoker quits?

Similarly lacking in much-needed specifics are the preventive items and services of alcohol misuse, diet counseling, obesity counseling, breast feeding interventions, and folic acid supplements for pregnant women.

## III. ALCOHOL MISUSE

With respect to alcohol misuse, the USPSTF recommends “screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings” as a grade “B” prevention service.

The Guide describes effective interventions as including initial counseling sessions, multi-contact interventions, further assistance, and follow-up that “can be delivered wholly or in part in the primary care setting, and by one or more members of the health care team, including physician and non-physician practitioners.”

Again, this makes it unclear as to what, specifically; must a health plan cover without imposing cost sharing, under the Rules of Section 2713? Must a health plan cover referral to counseling services with no office visit co-pay? Must a health plan cover specialty treatments such as in-patient substance abuse programs without cost sharing impositions?

## IV. HEALTHY DIET COUNSELING

With respect to diet counseling, the USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. “Intensive counseling delivered by primary care clinicians or by referral to other specialists such as nutritionists or dieticians” is a grade “B” recommendation.

The Guide recommends a number of approaches including medium- and lower-intensity face-to-face dietary counseling (in group or individual sessions) delivered by a nutritionist or by a specially trained primary care physician or nurse practitioner, supplemented by patient self-help materials, telephone counseling, or other interactive health communications.

Under these guidelines, may a health plan decide whether they will cover, at no cost, only group sessions versus individual sessions? Must appointments with nutritionists or dieticians be covered without office or specialty visit co-pays? How many sessions of these services must be covered before cost sharing is imposed, or must all sessions be covered indefinitely?

## V. OBESITY SCREENING AND COUNSELING

These same issues and questions can be raised with respect to the USPSTF's recommendations regarding obesity. The Guide rates with a "B" recommendation clinicians screening all adult patients for obesity and offering intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.

The Guide states that the most effective interventions combine nutrition education and diet and exercise counseling with behavioral strategies to help patients acquire the skills and supports needed to change eating patterns and to become physically active. The Guide also advises referring obese patients to programs that offer either high- or medium-intensity counseling and behavioral interventions for optimal weight loss.

In addition, the Guide discusses the use of pharmacological treatment of obesity, such as with Orlistat or sibutramine. Also recommended for certain obese populations are surgical interventions such as gastric bypass, vertical banded gastroplasty, and adjustable gastric banding. Re-operation may be necessary in up to 25 percent of these patients and the Guide recommends that surgical candidates receive a psychological evaluation prior to undergoing these procedures.

Must health plans cover diet, nutrition, and exercise counseling sessions without cost sharing and if so, how many or should they be covered indefinitely? Should pharmacological treatments be covered without co-pays and should surgical interventions be provided without cost sharing as well? Must health plans cover subsequent surgical interventions if the first surgery was not effective?

In determining the scope of items and services to be covered under the USPSTF's obesity recommendation, consideration should be given to the important role of a patient's commitment to sustained weight loss. Cost sharing can be an effective tool in ensuring that patients seeking surgical interventions to treat obesity are fully engaged and committed to the long-term success of such an intervention. I would urge the U.S. Health and Human Services Agency to consult with clinicians regarding the most effective approaches for ensuring that surgical interventions produce the desired long-term success.

## VI. BREASTFEEDING COUNSELING

With respect to the USPSTF's breastfeeding recommendations, grade "A" prevention services include multiple strategies such as formal breastfeeding education for mothers and families, peer support programs, and post- and prenatal education. Must a health plan cover all of these educational components, some, or none? Should both pre- and postnatal education be provided without cost sharing?

## VII. FOLIC ACID SUPPLEMENTATION

Regarding folic acid supplementation in pregnant women, the USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing specified amounts of folic acid. Must a health plan cover prescription folic acid supplements? What about over-

the-counter folic acid supplements? Should these supplements be covered for all child-bearing age women, per the recommendation, with no cost sharing?

#### VIII. OTHER RECOMMENDATIONS

Other USPSTF recommendations that need clarification include the use of aspirin to prevent cardiovascular disease, oral fluoride supplementation for children whose primary water source is deficient in fluoride, and iron supplementation for children at risk for iron deficiency anemia. Are health plans required to cover these supplements and over-the-counter items without cost sharing?

As you can see, there is a great need for clarification and specific information regarding these and other preventive care items and services to be covered under Section 2713. Any elucidation on the HHS' intentions and requirements would be most appreciated.

Again, the DMHC is very much in support of the focus on preventive health care services and is grateful for the opportunity to comment on the Rules. Should you have questions, please do not hesitate to contact me at (916) 322-2012, or [cehnes@dmhc.ca.gov](mailto:cehnes@dmhc.ca.gov).

Sincerely,

By



Timothy L. Le Bas  
Assistant Deputy Director  
Office of Legal Services

LUCINDA A. EHNES, ESQ.  
DIRECTOR  
CALIFORNIA DEPARTMENT OF MANAGED HEALTH CARE

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