

REG-120391-10

**LEGAL PROCESSING DIVISION
PUBLICATION & REGULATIONS
BRANCH**

PUBLIC SUBMISSION

As of: September 20, 2010
Received: September 17, 2010
Status: Posted
Posted: September 20, 2010
Tracking No. 80b51fef
Comments Due: September 17, 2010
Submission Type: Web

Docket: IRS-2010-0017

Requirement for Group Health Plans and Health Insurance Issuers to Provide Coverage of Preventive Services under the Patient Protection and Affordable Care Act

Comment On: IRS-2010-0017-0002

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services; etc.

Document: IRS-2010-0017-0031

Comment on FR Doc # 2010-17242

Submitter Information

Name: Richard Morgan Downey

Address:

4421 Yuma St. N.W.

Washington, DC, 20016

Email: mordowney@gmail.com

Phone: 202-957-0085

Organization: Downey Obesity Report

Government Agency Type: Federal

Government Agency: HHS

General Comment

RE: Interim Final Rules for Groups Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act, FR 75:41726, July 19, 2010

I would like to express support for the inclusions of coverage of preventive services, particularly that relating to obesity, for group health plans and health insurance issuers. Specifically, the interim final regulations incorporate the level B recommendation of the United States Preventive Services Task Force requiring intensive behavioral counseling of adults for obesity.

The background information makes clear that coverage of obesity prevention and reduction services can have extremely positive effects both for individuals and the country as a whole. The background information finds that even modest weight loss produces meaningful improvements in health and reductions in health care spending.

The USPSTF recommended high intensity counseling and found insufficient evidence for low or moderate counseling. Their recommendation states,

It is advisable to refer obese patients to programs that offer intensive counseling and behavioral interventions for optimal weight loss. The USPSTF defined intensity of counseling by the frequency of the intervention. A high-intensity intervention is more than 1 person-to-person (individual or group) session per month for at least the first 3 months of the intervention. A

medium-intensity intervention is a monthly intervention, and anything less frequent is a low-intensity intervention. There are limited data on the best place for these interventions to occur and on the composition of the multidisciplinary team that should deliver high-intensity interventions

This is the only specification of the minimum level of frequency, intensity and duration of services. The Overview Section of the regulations state that "These interim final regulations provide that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations." (At p.41828) Unfortunately, there is not an optimum medical management paradigm for the diverse population which will be covered by this recommendation. This may mean that many health plans will not have guidance on the level of frequency, intensity or duration of behavioral counseling adequate to meet the requirement for "intensive" and not moderate levels of counseling.

The National Institutes of Health funded multicenter clinical trial, LOOK AHEAD, is in the process of identifying optimal intensity and duration of treatment. Their research protocol provides:
For the first 6 months, one individual and three group session per month with a recommendation to replace two meals and one snack a day with liquid shakes and meal bars
For months 7-12, one individual and two group meetings per month and continue meal replacements

Starting at month 7, more intensive behavioral interventions as well as weight loss medications
Year 2-4, treatment on a monthly basis, including at least one on-site visit per month and a second contact by phone, email or mail. Short term-refresher groups and motivational campaigns are also offered three times yearly.

After year 4, participants are offered monthly individual visits, as well as one refresher group and one campaign a year. (see The Look AHEAD Study: a Description of the Lifestyle Intervention and the Evidence Supporting it, Obesity 2006 May;14(5):737-752)

This ongoing trial is producing significant reductions in weight loss and associated lipid and cardiovascular risk factors. (Wadden TA, et al, One Year Weight Losses in the Look AHEAD Study: Factors Associated with Success, Obesity (2009)17:713-722)

The final regulations direct group health plans and health insurance issuers to the ongoing results of the Look AHEAD trial to identify the optimal level of frequency, intensity and duration of intensive behavioral counseling. In the alternative, the USPSTF could be charged with updating their recommendation based on current clinical studies.

Thank you for this opportunity to comment.

Sincerely,

Morgan Downey, Publisher & Editor, Downey Obesity Report