

**LEGAL PROCESSING DIVISION
PUBLICATION & REGULATIONS
BRANCH**

REG-120391-10

SEP 20 2010

PUBLIC SUBMISSION

As of: September 20, 2010
Received: September 17, 2010
Status: Posted
Posted: September 20, 2010
Tracking No.: 80b51e96
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-2010-0017-0011

Comment on FR Doc # 2010-17242

Submitter Information

Name: Martha Brynne Saly

Address:

P.O. Box 1662

Rohnert Park, CA, 94927

Email: mbsaly@nvhr.org

Phone: 707-480-0596

Submitter's Representative: Martha Saly

Organization: National Viral Hepatitis Roundtable

General Comment

Please accept the attached comments regarding the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services (IRS-2010-0012-0002)

Thank you

Martha Saly

Attachments

IRS-2010-0017-0011.1: Comment on FR Doc # 2010-17242



2010 Steering Committee

Lorren Sandt (Chair)

Caring Ambassadors Program

Jeff Caballero (Vice Chair)

Association of Asian and Pacific
Community Health Organizations

Joan Block (Secretary)

Hepatitis B Foundation

Dennis Simon (Treasurer)

Hepatitis C Association

Bruce Burkett

Missouri Hepatitis C Alliance

Ryan Clary

Project Inform

Andrew Muir, MD

American Association for the Study
of Liver Disease

Michael Ninburg

Hepatitis Education Project

Daniel Raymond

Harm Reduction Project

Chris Taylor

National Alliance of State &

Territorial AIDS Directors

Deborah Wexler, MD

Immunization Action Coalition

Martha Saly

Director

P.O. Box 1662

Rohnert Park, CA 94927

707.480.0596

www.NVHR.org

NVHR is a project of
The Task Force for Global Health, Inc
Decatur, GA
www.taskforce.org

September 17, 2010

Office of Consumer Information and Oversight

Department of Health and Human Services

Attn: OCIO-9992-IFC

P.O. Box 8016

Baltimore, MD 21244-1850

Re: "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"

Dear Mr. Mayhew:

Thank you for inviting input regarding 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". I am writing to bring several issues to your attention regarding the use of evidence-based guidelines for preventive services.

In Public Health Service (PHS) Act Section 2713, and in the interim final regulations, insurers are required to provide benefits for and prohibit patient cost-sharing of:

- 1) those preventive services that have in effect a rating of "A" or "B" by the United States Preventive Services Task Force (USPSTF);
- 2) those child, adolescent, or adult immunizations that have a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the CDC; 3) those preventive services for infants, children, and adolescents provided for in the comprehensive guidelines of the Health Resources and Services Administration (HRSA); and
- 4) those preventive services for women that will be recommended by HRSA in 2011.

We commend the move towards evidence-based practices: the USPSTF has rated as "A" or "B" hepatitis screening for pregnant women and HIV testing of high risk adults. As a result, these services will be provided without patient cost-

The National Viral Hepatitis Roundtable is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States

sharing, in some cases for the first time. Similarly, we commend the regulations' support for Advisory Committee on Immunization Practices (ACIP) immunization guidelines, which include vaccination of at risk adults for hepatitis B. We also commend the proposed regulations for collecting information on risk factors and social, family, and medical history during the annual wellness visit.

We also commend your clarification that insurers may elect to cover those services that do not meet the threshold for provision without cost-sharing. However, we are concerned that the effect of this regulation will be that those preventive services not covered under PHS Act Section 2713 will be provided at a prohibitive cost or will be not covered at all.

There are several pertinent areas, including screening for viral hepatitis, in which the USPSTF has found insufficient evidence to recommend for or against a specific preventive service or has not given a preventive service an A or B ranking for the general population. In these areas, we would advocate that additional evidence-based guidelines, such as those developed by the CDC, be supported such that insurers are required to provide benefits and patient cost-sharing is prohibited.

Specific Examples

1) The USPSTF has rated as "D" the practice of screening the general population (not pregnant women) for hepatitis B virus (HBV). While we agree that screening the general population is not cost-effective, we advocate following CDC's recommendation that foreign-born individuals from countries where chronic HBV is at least 2% endemic be screened for HBV, along with those with behavioral risk factors, such as men who have sex with men (MSM) and injection drug users (IDUs).

3) The USPSTF has rated as "D" the practice of screening the general population (asymptomatic adults) who are not at increased risk for hepatitis C virus (HCV). We agree that screening the general population is not cost-effective. However, in 2012, CDC will likely update its screening guidelines to recommend one-time HCV screening for all adults born during 1945-1964, who have a higher prevalence of HCV than the general population and typically do not know they are infected. We would advocate the regulations allow for adopting these CDC guidelines in 2012.

5) The USPSTF has also found that there is insufficient evidence to recommend for or against routine screening for HCV in adults at high risk for infection. We would advocate following CDC's recommendation that people at high risk for HCV be screened, including anyone who received a blood transfusion prior to 1992 and anyone who has ever injected illicit drugs, even if it was many years ago.

We are concerned that preventive services on which USPSTF recommendations do not address the needs of groups for which CDC recommends risk-based screening (e.g., HBV screening for at-risk adults other than pregnant women and HCV screening for at-risk adults), because they are not required to be covered without cost-sharing, will not be covered by public or private insurers at all or will be provided with copays that are cost-prohibitive. In contrast, USPSTF defers to the recommendations of the CDC and ACIP regarding adult immunizations.

The National Viral Hepatitis Roundtable is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States

We therefore recommend adopting a similar policy, adding language to the regulations that guidelines from the CDC, the national prevention agency, be included for STD, HIV and Viral hepatitis screening in addition to the USPSTF guidelines when considering cost-sharing and reimbursement to avoid conflicting screening recommendations. We know if federal reimbursement policies do not align with CDC prevention recommendations, then the CDC guidelines will not be followed unless other funds are identified to cover the recommended services.

Thank you very much for considering this input.

Sincerely yours,



Martha Saly
Director



Lorren Sandt
Chair