



**National
Business
Group on
Health**

50 F Street, NW, Suite 600
Washington, D.C. 20001
202.628.9320 • Fax 202.628.9244
www.businessgrouphealth.org

Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

September 17, 2010

The Honorable Hilda L. Solis
Secretary
U.S. Department of Labor
Employee Benefits Security Administration
Office of Health Plan Standards and Compliance Assistance
Attention: RIN 1210-AB44
200 Constitution Avenue, N.W.
Room N-5653
Washington, DC 20210

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Attention: RIN 0938-AQ07
OCHIO-9992-IFC
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445G
Washington, DC 20201

The Honorable Timothy F. Geithner
Secretary
U.S. Department of the Treasury
Attention: RIN 1545-BJ60
Internal Revenue Service
1111 Constitution Avenue, N.W.
Room 5205
Washington, DC 20224

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 (Affordable Care Act).

Dear Secretaries Solis, Sebelius and Geithner:

The National Business Group on Health appreciates the opportunity to submit comments on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Affordable Care Act.

The National Business Group on Health represents approximately 298, primarily large, employers (including 64 of the Fortune 100) who voluntarily provide health benefits and other health programs to over 50 million American employees, retirees, and their families.

As you know, many employers voluntarily offer first-dollar coverage of preventive services to their employees and dependents and often provide coverage beyond the recommendations of the U.S. Preventive Services Task Force (USPSTF), when the clinical and medical evidence warrants it.

Effective measures exist today to prevent or delay much of chronic disease burden and curtail its devastating consequences. A focus on preventive medicine can dramatically reduce the incidence of, and long-term cost burden and health care demands of, chronic conditions. However, it is vital that the federal government continue to insulate the USPSTF, the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) from pressure to base preventive services recommendations on political motivation, provider interests, or pressure from advocacy groups. Rather, the government should ensure that they continue to base recommendations on sound clinical evidence and medical research on the effectiveness of screenings, interventions and other preventive care. The National Business Group on Health believes that encouraging evidence-based preventive care services will help identify people who are at high risk and help prevent, delay or reduce the adverse health consequences of preventable medical conditions and prevent further disability among people with established diseases.

In order to assist you with the administration of the Interim Final Rules, we make the following recommendations, which reflect the suggestions and concerns of our member companies:

- I. Ensure consistency between the Affordable Care Act and the IRS' definitions of preventive care services for Health Savings Account (HSA)-qualified health plans;**
- II. Clarify that plans with health accounts can provide first-dollar coverage for over the counter (OTC) drugs if recommended by the USPSTF, the CDC or HRSA;**
- III. Clarify that plans can continue to set coverage limits based on reasonable medical management techniques when the USPSTF, CDC or HRSA recommendations provide a range for the frequency, method, treatment or setting of preventive care services and also account for geographic variations in practice;**
- IV. Allow plans to continue to set coverage limitations based on reasonable medical management techniques for specific counseling and behavioral interventions recommended by the USPSTF, the CDC and HRSA; and**

- V. **Allow plans to continue to foster better quality, efficacy and efficiency through value-based insurance designs by allowing patient cost sharing for preventive services delivered by out-of-network and lower performing providers.**

I. Ensure consistency between the Affordable Care Act and the IRS' definitions of preventive care services for Health Savings Account (HSA)-qualified health plans

Recommendation: The Departments should ensure consistency between the Affordable Care Act and the IRS' definitions in the preventive care services “safe harbor” for HSA-qualified High-Deductible Health Plans (HDHPs). We recommend that the IRS “safe harbor” for HSA-qualified HDHPs automatically include any preventive care services covered by the requirements in these regulations.

According to the 2010 Kaiser/HRET Survey of Employer Sponsored Health Benefits, 92% of employers who offer HSA-qualified HDHPs covered preventive care before plan participants meet the deductible.

Generally, HSA-qualified HDHPs cannot provide any benefits before the deductible is satisfied, unless the benefits are for preventive care services. To aid plans in determining what plans can pay for before plan participants meet their deductibles, the IRS has created a “safe harbor” exception for preventive care services. The IRS preventive care services under the “safe harbor” include, but are not limited to, periodic health evaluations, including tests and diagnostic procedures ordered in connection with routine examinations, such as annual physicals; routine prenatal and well-child care; child and adult immunizations; tobacco cessation programs; obesity weight-loss programs; and screening services (cancer, heart and vascular diseases; infectious diseases; mental health conditions; substance abuse; metabolic, nutritional or endocrine disorders; musculoskeletal disorders; obstetric and gynecological conditions; pediatric conditions; and vision and hearing disorders).

As you know, the Affordable Care Act provides a different definition of preventive care services and requires first-dollar coverage for all USPSTF recommendations that have a an “A” or “B” current rating; CDC-approved immunizations and HRSA guidelines for women, infants, children and adolescents.

The Departments need to maintain consistency between the Affordable Care Act and the IRS to ensure a uniform “safe harbor” for preventive care services offered by HSA-qualified HDHP plans and provide clear guidance to plans, employers, providers and consumers.

II. Clarify that plans with health accounts can provide first-dollar coverage for OTC drugs if recommended by the USPSTF, the CDC or HRSA

Recommendation: The Departments should permit consumers to use health accounts to purchase OTC drugs without adverse tax consequences if they are recommended by the USPSTF, CDC or HRSA, based on evidence of effectiveness.

The USPSTF recommends coverage of aspirin for men and women over certain ages to prevent cardiovascular disease, which means that non-grandfathered plans must cover and pay for aspirin on a first-dollar basis. However, the USPSTF's recommendation seems at odds with the Affordable Care Act's ban on using Flexible Spending Accounts (FSAs), HSAs or FSA and HRA debit cards to purchase over-the-counter (OTC) drugs without a prescription, beginning in 2011. *Health plans, including FSAs and HSA-qualified HDHPs, seek clarification from the Departments to ensure that they can cover all of the recommendations from the USPSTF, CDC or HRSA, including recommended OTC drugs.*

III. Clarify that plans can continue to set coverage limits based on reasonable medical management techniques when the USPSTF, CDC or HRSA recommendations provide a range for the frequency, method, treatment or setting of preventive care services and also account for geographic variations in practice

Recommendation: The Departments should deem employers and plans in compliance with the regulations that set acceptable coverage limits when the USPSTF, CDC or HRSA recommendations include ranges for the frequency, method, treatment or settings for preventive care services or to account for geographic practice variations.

The National Business Group on Health strongly supports the provision in the interim final regulations that allows plans to continue to use reasonable medical management techniques and the relevant evidence base to determine the frequency, methods, treatments, or settings for recommended preventive services (without cost-sharing) to the extent not specified in recommendations or guidelines.

We commend the Departments' acknowledgment that "the use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived." However, we are requesting clarification when the government specifies a range for the frequency of a recommended preventive care service that plans may still determine the coverage limitations as long as they are within the recommended range. For example, the USPSTF provides a "B" recommendation for screening mammography for women with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older. Since the USPSTF provides a recommended range for mammography screening, the Departments should allow plans to cover them every 2 years and still remain in compliance with the regulations.

We also ask that where accepted geographic variations in physician practice for preventive services exist, that plans have the flexibility to take that into account as part of reasonable medical management techniques. For example, the USPSTF recommends colonoscopies, in adults, beginning at age 50 and continuing until age 75. The recommendation does not specify which type of colonoscopy or what accompanying services need to be provided. Some physicians in certain geographic areas routinely use monitored anesthesia care (MAC) during colonoscopies for patients without sedation-related risk factors. Other areas of the country and other physicians do not. Accordingly, the Departments should allow plans to limit coverage for MAC for routine colonoscopies in areas where it is not the general practice since there is no universally accepted evidence that average-risk patients require it and anesthesia charges may run as high as \$600 to \$800 per patient.

The Medicare program provides a precedent for permitting coverage to vary by region. Studies by the Dartmouth Atlas have confirmed differences in practice patterns, recommended treatments and styles across the country and the Medicare program. Recognizing this variation, Medicare has decentralized coverage and regions are permitted some flexibility in what services or components of services are covered.

IV. Allow plans to continue to set coverage limitations based on reasonable medical management techniques for specific counseling and behavioral interventions recommended by the USPSTF, the CDC and HRSA

Recommendation: The Departments should ensure that plans can continue to define which counseling and behavioral interventions will receive first-dollar coverage and to continue to be able to set coverage limitations based on reasonable medical management techniques (visit limits, steering to select providers, requiring treatment with other options before being eligible for a service, etc.) within the parameters of the recommendations of the USPSTF, the CDC and HRSA.

The current USPSTF recommendations for “counseling” services are vague, open-ended and allow for a broad interpretation that lacks any specific requirements to identify high-quality providers with established histories of evidence-based outcomes. For example, the USPSTF provides a “B” rating for “intensive counseling and behavioral interventions to promote sustained weight loss for obese adults” with similar recommendations for “counseling” to prevent obesity in children, sexually transmitted infections, tobacco use, alcohol misuse and “counseling” for a healthy diet. Therefore, employers and plans can not implement these recommendations in the same way as vaccinations or other one-time preventive care services. In addition, at some point, “counseling” moves beyond prevention and constitutes treatment.

Employers and plans have a plethora of experience in identifying high-quality providers for “counseling” and evidence-based behavioral interventions and treatments. For example, medical evidence shows that the key to success for some weight loss

interventions is prior counseling. There are many other sound medical management techniques required of some interventions before resorting to other, usually more invasive and more risky procedures. For example, bariatric surgery candidates must first undergo psychiatric counseling, meet with a nutritionist to change their diet and lose up to 10% of their weight in order to better control existing obesity related medical problems such as diabetes, sleep apnea and fatty liver before they are eligible for surgery. Accordingly, the Departments should ensure that employers and plans can select recommended interventions to receive first-dollar coverage and set coverage limitations for other interventions based on medical evidence and clinical-effectiveness and particularly where the service goes beyond prevention and constitutes treatment. This would assure plans that they can continue to select high-quality, certified “counseling” providers and other providers and still comply with the regulation.

V. Allow plans and insurers to continue to foster better quality and efficiency through value-based insurance designs by allowing patient cost sharing for preventive services delivered by out-of-network and lower performing providers

Recommendation: The Departments should continue to allow plans to maintain patient cost sharing for preventive services delivered by out-of-network providers to help drive patients to higher-quality providers to improve health care outcomes.

Recommendation: The Departments could also enhance value-based benefit and insurance designs by continuing to permit cost-sharing for providers with lower performances on quality assurance programs, poorer ratings on patient safety measures (such as those endorsed by the National Quality Forum (NQF)) and providers who are not connected to patient-centered medical homes.

The Interim Final Rules permit plans and issuers to implement designs that seek to foster better quality, effectiveness and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. Specifically, the Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

We strongly support permitting plans and issuers to foster better quality and efficiency by allowing patient cost sharing for preventive services delivered by out-of-network providers. Employers and plans select network providers based on criteria designed to enhance quality, efficiency, patient safety and convenience. Out-of-network providers may not meet these standards. For example, criteria for imaging providers often include the following:

- Quality Assurance
 - Accreditation requirements (American College of Radiology (ACR), Intersocietal Accreditation Commission (IAC), Joint Commission on Accreditation of Healthcare Organizations (JCAHO));
 - Quality Assurance (QA) programs in place; and
 - Safety programs in place.
- Equipment
 - Age of equipment; and
 - Appropriateness of equipment to exam screenings.
- Staffing
 - Board certified physicians;
 - Modality certified technicians; and
 - Volume of exams.
- Service
 - Accessibility; and
 - Hours.

In another example, many employers and plans only cover genetic tests performed by laboratories certified by the Clinical Laboratory Improvement Amendments (CLIA).

The National Business Group Health also believes that CMS should increase reimbursements to primary care providers who form partnerships with their patients, coordinate services across specialties and advise patients on preventive care through patient-centered medical homes. Physicians not connected to medical homes may not meet these standards and can fragment care between multiple providers where keeping up-to-date on preventive care can be difficult, particularly for those with special needs or complex medical conditions. Plans based on the medical home model should be permitted to require cost-sharing for preventive services not provided through medical homes to encourage plan participants to receive these services through medical homes where they would not have any cost-sharing.

The Departments can promote higher-quality care and ultimately better health outcomes by allowing plans to require patient cost sharing for preventive services delivered by out-of-network providers and for lower-performing providers on quality assurance and patient safety programs, and providers who are not part of patient-centered medical homes.

Thank you for considering our comments and recommendations on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Affordable Care Act. We look forward to continuing to work with you as you implement the various provisions of the new law. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 585-1812, if you would like to discuss our comments in more detail.

Sincerely,

A handwritten signature in black ink that reads "Helen Darling". The signature is written in a cursive, flowing style.

Helen Darling
President

cc: The Honorable Phyllis C. Borzi, Assistant Secretary, Employee Benefits and
Security Administration (EBSA)
Mr. Jay Angoff, Director, Office of Consumer and Insurance Oversight (OCIO)
The Honorable Douglas H. Shulman, Commissioner, Internal Revenue Service
(IRS)
Ms. Amy Turner, EBSA
Ms. Beth Baum, EBSA
Ms. Karen Levin, IRS
Mr. Jim Mayhew, OCIO