September 17, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Attention: RIN 1210-AB44

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

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

Dear Sir or Madam:

I am writing to submit comments on behalf of the American Benefits Council ("Council") on 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 ("Interim Final Rules"), which were published by the Departments of Labor, Health and Human Services, and the Treasury ("Agencies") on July 19, 2010 (75 Fed. Reg. 41,726).

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to retirement and health plans that cover more than 100 million Americans. Our members typically include preventive care coverage in their group health plans. Such coverage is highly valued by employers and their employees and dependents as a means of promoting health and improving productivity. In fact, many of our members have been important innovators in coverage of preventive care, often as a component of their wellness and other health promotion programs

The Interim Final Rules provide essential guidance for employers and issuers as they work to comply with the statutory requirements. They Interim Final Rules implement section 1001 of the Patient Protection and Affordable Care Act ("PPACA"), which added new section 2713 to the Public Health Service Act ("PHSA"). New PHSA section 2713 requires group health plans and health insurance issuers to provide coverage for, and not impose any cost-sharing requirements with respect to, certain preventive services and medications identified in certain recommendations and guidelines developed for use in a clinical practice setting ("Recommended Preventive Services").

Our comments and specific recommendations for clarification regarding the Interim Final Regulations are set out below. It is our understanding that these comments will be shared with the Departments of the Treasury and Health and Human Services.

Additional Guidance Is Requested Regarding Recommended Preventive Services

As noted above, new PHSA section 2713 requires group health plans and health insurance issuers to provide coverage for, and not impose any cost-sharing requirements with respect to, Recommended Preventive Services. The Recommended Preventive Services, established by the United States Preventive Services Task Force ("Task Force"), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention ("Advisory Committee"), and the Health Resources and Services Administration ("HRSA"), were developed for use by physicians and other providers for clinical decision making. Since the Recommended Preventive Services were not developed for the purpose of establishing an enumerated list of mandated plan benefits and/or coverage policies, using them for that purpose raises interpretive issues for plans.

Given the importance of resolving these interpretive issues, we request the specific clarification described below. Moreover, with respect to interpretive issues not specifically addressed below, we request that plans and issuers be permitted to make good-faith use of "reasonable medical management techniques" (as described in the Interim Final Rules) to resolve any ambiguities that may arise in connection with applying the lists of Recommended Preventive Services.

Clarification regarding counseling provided through an appropriate wellness program or Employee Assistance Program. Certain of the items included on the Recommended Preventive Services lists pertain to "counseling". For example, the recommendations provided by the Task Force include "[c]ounseling for tobacco use" and "recommend[] that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products."[1]

[1] http://www.healthcare.gov/center/regulations/prevention/taskforce.html

Employers in increasing numbers are offering wellness programs or Employee Assistance Programs (EAPs) to their employees. These programs, in many instances, do and/or will provide counseling services for many of the Recommended Preventive Services. Counseling may be provided through different formats intended to make services easily accessible and effective for plan participants, including on-line and telephonic programs. These programs often include the provision of services by health care professionals who specialize in specific types of counseling, such as tobacco cessation or alcohol misuse. Given the specialized nature of the counseling, these professionals provide services that may be more effective than a primary care provider who may lack such expertise or may have less time during an office visit to focus solely on counseling needs.

Accordingly, we request clarification that, where appropriate, employers may satisfy the requirement to provide specific counseling services as part of their group health plans by offering appropriate wellness programs or EAPs, and that a plan may use reasonable medical management techniques to determine if the employer's wellness program or EAP satisfies the recommendations.

Clarification is needed that Recommended Preventive Services pertaining to counseling with respect to the usage of medications do not require first-dollar coverage of the medication in addition to the counseling service. Certain of the Recommended Preventive Services pertain to counseling regarding the use of over-the-counter or prescription medicines. For example, among other recommendations, the Task Force recommends "[s]upplementation with folic acid" and "recommends that all women . . . take a daily supplement . . . of folic acid".[2] This raises another issue that would benefit from clarifying guidance; specifically, whether the Recommended Preventive Services pertain only to the counseling provided by the licensed practitioner, or whether it also encompasses the related recommended medication at issue (*e.g.*, aspirin).

For several reasons, the Council requests clarification that the Recommended Preventive Service is limited to the counseling only and does not also encompass the related recommended medication, drug or supplement. First, and perhaps foremost, treatment of a condition that is manifested or otherwise clinically apparent is not preventive care. This view was expressly stated by the Internal Revenue Service ("IRS") in connection with guidance it provided regarding what constitutes preventive care services for purposes of the preventive care deductible safe harbor that applies to high deductible health plans under Internal Revenue Code section 223(c)(2)(C) (regarding health savings accounts ("HSAs")). Specifically, the IRS, in defining what constitutes a preventive care service, stated that "the preventive care safe harbor under section 223(c)(2)(C) *does not include* any service or benefit intended to treat an existing illness, injury, or condition, including *drugs or medications used to treat an existing illness, injury or*

[2] *Id*.

condition."[3] The rule adopted by the IRS with respect to HSAs should also apply here as the reasoning underlying such rule is sound.

Additionally, a contrary rule could require a plan to cover items that are taxable to the employee. Section 9003 of PPACA amended Internal Revenue Code section 106, which applies to all employer-provided plans, to prohibit the reimbursement of over-the-counter drug and medicine expenses from all employer-provided plans for expenses incurred after December 31, 2010. Thus, plans generally will no longer be permitted to reimburse over-the-counter drugs and medicines (*e.g.*, aspirin). Therefore, to the extent that the over-the-counter drug itself constitutes a preventive care service, this would compel plans to violate new Internal Revenue Code section 106. Certainly Congress did not intend for this result when it enacted PPACA sections 9003 and 2713.

For these reasons, we request clarification that the Recommended Preventive Service is limited to the counseling only and does not encompass the related drug or medication.

Clarification is needed that the requirement for a plan to offer a service without cost-sharing is limited to the specific Recommended Preventive Service and does not apply to any course of treatment that may follow. The Recommended Preventive Services include certain recommended screenings, such as screenings for breast cancer. Clarification is needed that the preventive service subject to the no cost-sharing requirement pertains only to the screening itself and does not include any subsequent course of treatment that could result from the screening. For example, the Recommended Preventive Services should be limited to the screening itself (such as a screening for high blood pressure) and should not include any follow-up course of treatment for high blood pressure (such as a mandated course of drug treatment to help control or reduce an individual's high blood pressure or any other medical intervention that could result).

This issue is even more acute with respect to the recommended screening for depression as contained in the list maintained by the Task Force. Not only does it reference screening, it also expressly references "effective treatment, and follow-up". This reference to treatment and follow-up adds to the uncertainty of whether a plan must offer these benefits without cost-sharing, and may cause confusion among plan participants and providers.

For reasons similar to those discussed above, we request expanded guidance clarifying that a plan need only provide the specific preventive screening described in the recommendation without cost-sharing and is not otherwise required to (i) provide coverage for any treatment that may result from the screening, or (ii) provide such subsequent treatment without cost-sharing.

[3] IRS Notice 2004-50, Q&A 27 (emphasis added).

The Council supports the rule permitting the use of reasonable medical management techniques by plans and issuers and requests that such rule be restated as part of any future guidance. The Interim Final Rules provide that a plan may use "reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service . . . to the extent not specified in the recommendation or guideline."[4] The Council strongly supports permitting plans and issuers to rely on reasonable medical management techniques in applying the Interim Final Rules in connection with their health plan offerings.

We believe such a rule is particularly warranted, given that the list of Recommended Preventive Services is dynamic and subject to regular changes. These changes are likely to result in additional ambiguities will also need to be interpreted and resolved by plans and issuers. It is unrealistic (and perhaps even undesirable from a policy/fiscal perspective) to expect the Agencies to have the resources to monitor and clarify in formal written guidance all ambiguities that arise with respect to a changing list of Recommended Preventive Services. Therefore, the rule set forth in the Interim Final Rules allowing for the use of reasonable medical management techniques will provide plans and issuers with the flexibility necessary for compliance with the Interim Final Rules on a going-forward basis.

Given the importance of this rule for plans and issuers in complying with the Interim Final Rules, we encourage the Agencies as part of any future rulemaking to include a restatement that makes clear that a plan or issuer may rely on reasonable medical management techniques in applying and interpreting the Recommended Preventive Services, including for purposes of resolving any ambiguities that may arise.

Clarification of an Insurer's Determination of the "Primary Purpose" of an Office Visit

The Interim Final Rules include specific rules regarding when a plan may impose cost-sharing if a Recommended Preventive Service is provided during an office visit. If a Recommended Preventive Service is billed separately from the office visit, the plan may impose cost-sharing with respect to the office visit. However, if the Recommended Preventive Service and the office visit are billed together, then the plan may only impose cost-sharing if the Recommended Preventive Service is not the *primary purpose* of the office visit. Specifically, the Interim Final Rule provides:

> (i) If [a Recommended Preventive Service] is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

[4] Temp. Treas. Reg. § 54.9815-2713T(a)(4); 29 C.F.R. § 2590.715-2713(a)(4); 45 C.F.R. § 147.130(a)(4).

(ii) If [a Recommended Preventive Service] is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If [a Recommended Preventive Service] is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.[5]

A rule that turns on a determination of the primary purpose of the office visit requires information regarding the substance of the visit to be properly documented by the provider and transmitted to the insurer. This, of course, depends, in turn, on (i) the availability of billing codes designed to transmit information relevant to the primary purpose determination, and (ii) the widespread understanding by health care providers regarding the use of correct billing practices and the importance thereof.

We recommend that the Agencies clarify that unless a plan or issuer has actual knowledge that the primary purpose of an office visit was to receive a Recommended Preventive Service (*e.g.*, where the billing codes clearly indicate this to be the case), the plan or issuer may impose cost-sharing with respect to the office visit. This rule is necessary for those instances where they receive ambiguous billing information and will ensure that plans and issuers can quickly and efficiently administer the primary purpose rule. A contrary rule would operate to mandate first-dollar coverage for items other than Recommended Preventive Services and would likely result in increased plan costs and, in turn, higher premiums for employees and employers. Moreover, the proposed clarification is likely to be of special importance in the near-term unless and until billing practices and medical codes are modified and updated with an eye towards exchanging the information necessary for the full and complete administration of the primary purpose rule.

We also suggest that the Agencies conduct outreach to the health provider community regarding the statutory preventive services coverage requirements and regulatory guidance. Proper coding of services by providers is essential in order to avoid confusion for participants regarding any cost-sharing requirements under the plan. Many services can be preventive, diagnostic or treatment, depending on the clinical circumstances. Improper coding of a mammogram, for example, that was for screening purposes but incorrectly coded by the provider as diagnostic, could cause a participant to be erroneously subject to cost-sharing under a plan.

[5] Temp. Treas. Reg. § 54.9815-2713T(a)(2), 29 C.F.R. § 2590.715-2713(a)(2), 45 C.F.R. §147.130(a)(2).

Clarification is Needed Regarding the Interaction Between the Preventive Services Requirements and Mental Health Parity Requirements

The overwhelming majority of our employer members include comprehensive coverage for behavioral health or substance use disorders in their group health plans. It is important to note, however, that there may be some employers that may not offer such coverage. As discussed below, we believe those employers could be required to do so as an unintended consequence of their compliance with the Interim Final Regulations.

The Recommended Preventive Services include some services that are likely to qualify as "mental health or substance use disorder benefits" under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the "MHPAEA"), including counseling for alcohol misuse and tobacco use and screenings for depression. We request clarification that plans and issuers that provide mental health or substance use disorder benefits to the extent required to comply with the Interim Final Rules shall not be deemed to have voluntarily subjected themselves to the requirements of the MHPAEA such that they now have to provide for an expanded menu of mental health and substance use disorder benefits.

Generally, the MHPAEA requires that, if a plan provides mental health benefits, it must provide parity between such benefits and any medical or surgical benefits offered under the plan. Significantly, the MHPAEA does not require plans to provide for any mental health benefits at all; however, if a plan does provide coverage for some mental health benefits, it must provide such coverage on an equal basis with respect to medical/surgical benefits. This includes both the extent of coverage (based on seven categories of coverage) and any related financial cost-sharing. For example, to the extent that a plan provides medical/surgical benefits for in-patient/in-network, in-patient/out-of-network, out-patient/in-network, emergency care and prescription drugs**,** and chooses to offer mental health benefits with respect to in-patient/in-network, then it must also offer mental health benefits for in-patient/out-of-network, out-patient/in-network, emergency care and prescription drugs. Significantly, as noted above, a plan can provide for no mental health benefits at all.

The issue that arises with respect to the MHPAEA is that the list of Recommended Preventive Services appears to require plans to provide some mental health benefits. For example, the Task Force list recommends "screening and behavioral counseling interventions to reduce alcohol misuse".[6] It appears that, in order to comply with PPACA and the Interim Final Rules, a plan must provide some amount of mental health benefits. Thus, there is a question as to whether, by complying with the Interim Final Rules, a plan or issuer could subject itself to MHPAEA's requirements, and thus, as a result, be obligated to provide a broad array of mental health benefits.

[6] http://www.healthcare.gov/center/regulations/prevention/taskforce.html

The Council does not believe that Congress intended for plans to become subject to the MHPAEA's requirements solely by complying with the preventive services requirements. The MHPAEA clearly states that it is not to be construed to require plans to provide mental health or substance use disorder benefits[7] and therefore a plan could choose whether to subject itself to the requirements of the MHPAEA. Specifically, it states that "[n]othing in this section shall be construed . . . as requiring a group health plan to provide any mental health or substance use disorder benefits".[8] Furthermore, if compliance with the Interim Final Rules were to subject a plan or issuer to the MHPAEA, this would in the vast majority of instances result in the plan or issuer having to provide some out-of-network mental health benefits. This is because, to the extent that a plan or policy provided for out-of-network medical/surgical benefits (which almost all do), the plan or policy would be required under the MHPAEA to provide out-of-network mental health benefits. Such a result would be in direct conflict with the Interim Final Rules, which states that "[n]othing in this section requires a plan or issuer that has a network of providers to provide benefits . . . that are delivered by an out-of-network provider."[9]

Based on the foregoing, we request clarification that to the extent that a plan provides mental health benefits solely to comply with PPACA, the plan is deemed to not be subject to the mental health parity requirements. Such a clarification is needed to ensure that plans may comply with the Interim Final Rules as intended, *i.e.*, on an in-network basis, without fear of being subject to expanded mental health benefit obligations by reason of the MHPAEA.

Request for a Good Faith Compliance Standard

Plans are working as expeditiously as possible to implement the Interim Final Rules. Although plans are making their best efforts to bring any and all related systems up-to-date and coordinate with all necessary third-party service providers, the implementation of the Rules is a complicated process and requires time. We respectfully request that the Agencies issue timely guidance indicating that, for purposes of enforcement, the Agencies will take into account good faith efforts to comply with the Interim Final Rules. Specifically, we request a standard similar to the good faith standard promulgated for purposes of interpreting the term "essential health benefits".[10]

We believe a good faith standard is warranted given the necessary coordination that must occur by and between plans/issuers and multiple third parties, as well as likely needed changes to enrollment and benefit administration systems, policies, and written

[7] IRC § 9812(b); ERISA § 712(b); PHSA § 2726.
[8] *Id*.
[9] Temp. Treas. Reg. § 54.9815-2713T(a)(3); 29 C.F.R. § 2590.715-2713(a)(3); 45 C.F.R. § 147.130(a)(3).
[10] 75 Fed. Reg. 37,191.

materials. Understandably, such coordination takes some time, especially in light of the fact that many of these same entities are already using all available resources with respect to complying the numerous other PPACA provisions that share a September 23, 2010 effective date.

Accordingly, the Council requests timely guidance providing for the establishment of a good faith standard to ensure that employers are not unfairly penalized notwithstanding their efforts to comply with the Interim Final Rules.

Issuance of an Annual List of Recommended Preventive Services

The Council requests that the Department of Health and Human Services issue a comprehensive annual list of Recommended Preventive Services for use by plans and issuers in complying with the Interim Final Rules. As previously addressed, the Recommended Preventive Services are established by three expert entities: the Task Force, the Advisory Committee and the HRSA. The three entities publish and update four separate lists which together comprise the Recommended Preventive Services. These lists are updated at various times throughout the year. Under the terms of the Interim Final Rules, as promulgated, Plans must now keep track of any additions or deletions made to each of the four lists in order to provide the appropriate Recommended Preventive Services. We appreciate that the Department of Health and Human Services has established a dedicated website which provides links to each of the lists of recommendations and it appears that the Department intends to highlight additions to the Recommended Preventive Services. Although this is indeed helpful, the issuance of a comprehensive annual list of Recommended Preventive Services would provide plans and issuers with an important compliance tool.

Additional Guidelines for Value-Based Insurance Design

As discussed in the Preamble to the Interim Final Rules, the Affordable Care Act granted the Agencies authority to develop guidelines for group health plans and health insurance issuers to utilize "value-based insurance design"[11] as part of their offering of preventive health services.

We support and commend the Agencies for their express recognition of the important role that value-based insurance design can play in promoting the use of appropriate preventive services. We strongly recommend that any final regulations retain the provision in the Interim Final Regulations permits plans and issuers to implements such designs by not requiring them provide preventive services coverage on an out-of-network basis and to the extent they do so, allow cost-sharing while eliminating cost-

[11] According the Preamble, value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers.

sharing for recommended preventive health services delivered on an in-network basis. The Council also supports the development of additional guidelines for value-based insurance designs that ensure value and quality, while ensuring access to evidence-based preventive services.

Thank you for the opportunity to comment on the Interim Final Regulations and for considering our recommendations. Please contact me at kwilber@abcstaff.org or 202-289-6700 with any questions or if we can be of further assistance.

Sincerely,

Kathryn Wilber
Senior Counsel, Health Policy
American Benefits Council