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***Submitted Via Federal Rulemaking Portal: <http://www.regulations.gov>***

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  
Attn: RIN 1210-AB44

***RE: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Coverage of Preventive Services the Patient Protection and Affordable Care Act***

To Whom It May Concern:

The U.S. Chamber of Commerce (the “Chamber”) is submitting these comments in response to the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (“IFRs” or “regulations”), which were published in the Federal Register on July 19, 2010.<sup>1</sup> The IFRs provide guidance pursuant to the statutory language of §2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act (the “Affordable Care Act”). As with other guidance under these Acts, the IFRs were published jointly by the Department of the Treasury, the Department of Labor and the Department of Health and Human Services (the “Departments”).<sup>2</sup>

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. These comments have been developed with the input of member companies with an interest in improving the health care system.

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<sup>1</sup> Group Health Plans and Health Insurance Coverage Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726–60 (July 19, 2010) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147) [hereinafter Preventive Service Coverage].

<sup>2</sup> Pursuant to the request in the IFRs, the Chamber is submitting these comments to one of the Departments - The Department of Labor, with the understanding that these comments will be shared with the Department of Health and Human Services and the Department of Treasury as well.

## **OVERVIEW**

For nearly a decade, the Chamber has focused specifically on helping employers improve the health of their workforce. In addition to providing coverage for medical treatment for employees and dependents, the Chamber and its member companies appreciate the importance of investing in prevention to improve and maintain health proactively. We hope that these regulations, and the statutory requirements that led to their promulgation, will be a step toward encouraging the adoption of evidence-based medicine and increasing access to evidence-based clinical preventive services.

However, although we support the goals of these regulations, we are concerned with some aspects of the IFRs:

- First, we have some implementation concerns regarding the permitted use of medical management techniques to comply with preventive service coverage requirements where the preventive guidelines do not definitively state the scope, setting or frequency of items/services required to be covered.<sup>3</sup>
- Secondly, with regard to the process plans follow when preventive services are removed from the recommended guideline lists, the regulations undermine their own provisions intended to protect plans from the need to incessantly monitor the prevention guidelines as issued by the three different issuing entities – United States Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the Health Resources and Services Administration.
- Third, although we agree with and support the clarification that required first dollar coverage for preventive services does not extend to treatment, we are concerned about the significant practical ramifications that plans will face when making this distinction.
- Fourth, there are some discrepancies between the regulations and current tax provisions that need to be clarified.

## **LAUDABLE GOALS**

The Chamber supports the policy goals behind covering preventive services in general and concurs with many of the implementation approaches taken by the regulations. We agree with the Departments' assessment of the benefits that can be anticipated from these interim final regulations.<sup>4</sup> We appreciate the attention to, as well as interest in<sup>5</sup>, encouraging value-based

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<sup>3</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,728-9. "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."

<sup>4</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,733. "First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs. Fourth, the cost of preventive services will be distributed more equitably."

insurance design.<sup>6</sup> We applaud the Departments' recognition of scenarios where first dollar coverage of preventive services is not appropriate<sup>7</sup> and agree that, in these instances, cost sharing must be permitted<sup>8</sup> and coverage may be denied<sup>9</sup> to encourage the adoption of value based insurance design measures. Generally, we believe the Departments have appropriately interpreted the statute without undermining the ability of plans or employers to incent quality and reward participating providers. However, several important implementation issues must be further clarified in the final regulation to ensure the fulfillment of these goals.

## **IMPLEMENTATION CONCERNS**

The Chamber appreciates efforts to create flexibility and to preserve the choice of employers in making plans decisions. As noted in the regulations, a substantial majority of employers are already providing first dollar coverage for preventive services.<sup>10</sup> Our concerns relate to penalties that employers face for inadvertent noncompliance given some of the ambiguities. With the significant penalty of \$100 per day per enrollee for each failure to comply with the requirement to provide first dollar preventive services coverage, as well as the costly burden created by the external review and appeals provisions, employers need clarity when possible.

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<sup>5</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,729. "The Departments are developing additional guidelines regarding the utilization of value based insurance designs...[and]...are seeking comments related to the development of such guidelines... that promote consumer choice of providers or services that offer the best value and quality while ensuring access to critical, evidence-based preventive services."

<sup>6</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,729. "These interim final regulations permit plans and issuers to implement designs that seek to foster better quality 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."

<sup>7</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,738 "Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application... creating financial incentives for consumers to request preventive services at office visits intended for other purposes."

"Requiring coverage by out-of-network providers at no cost sharing would result in higher premiums. Plans and issuers negotiate allowed charges with in-network providers. Allowing zero cost sharing for out-of-network providers could reduce providers' incentives to participate in insurer networks."

<sup>8</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,758

(to be codified at 29 C.F.R. §2590.715-2713 (a)(2)(i)) "If [preventive] item or service is billed separately from an office visit, an issuer or plan may impose cost sharing [for the] office visit.")

(to be codified at 29 C.F.R. §2590.715-2713 (a)(2)(iii)) "If [preventive] item or service is not billed separately from an office visit and the primary purpose of the office visit is not the delivery of such [preventive service], a issuer or plan may impose cost sharing [for the] office visit.")

(to be codified at 29 C.F.R. §2590.715-2713 (a)(3)) "[N]othing ...precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for [preventive] items or services delivered by an out-of-network provider."

<sup>9</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,758 (to be codified at 29 C.F.R. §2590.715-2713 (a)(3)) "Out-of-network Providers – Nothing in this section requires a plan or issuer, that has a network of providers, to provide benefits for [preventive] items or services that are delivered by an out-of-network provider."

<sup>10</sup> Preventive Service Coverage, 75 Fed. Reg. at 41732. "According to a 2009 survey of employer health benefits, over 85 percent of employer sponsored health insurance plans covered preventive services without having to meet a deductible."

## 1. Complying with Guidelines

The Chamber has two areas of concern with regard to how plans comply with preventive service coverage requirements.<sup>11</sup>

- First, regulations should clarify that mandated first dollar coverage of preventive services is only required for the minimum frequency stated in the guidelines.
- Second, additional guidance and regulations are expected to define medical loss ratio in the future. With the regulations acknowledgement of the importance of medical management, it would be inappropriate to include a plan's medical management costs in the category of administrative expenses when calculating medical loss ratio. Core components of medical management services include utilization management, case management and disease management.<sup>12</sup> To force plans to include costs associated with these programs as an administrative expense when calculating medical loss ratio would effectively penalize plans for relying on techniques acknowledged by the Departments as necessary.

## 2. Changing Recommendations and Guidelines

We appreciate the explanation in the preamble relating to new guidelines and efforts to minimize the burden on plans and issuers in remaining current as to preventive services for which guidelines require first dollar coverage.<sup>13</sup> However, as also noted in the preamble and in the regulations, plans must give “60 days advance notice to an enrollee before any material modification will become effective.”<sup>14, 15</sup> While plans are “not required to provide coverage<sup>16</sup>” (or according to the preamble - waive cost sharing requirements) for any item that ceases to be a recommended preventive service, it is not clear if plans may cease to do so after providing advance notice in the middle of a plan year. For example, if a guideline is removed from the recommended preventive service list in February and after a plan that begins in January provides the requisite 60 day notice to its enrollees, it is not clear if a plan may stop providing coverage and/or begin imposing cost sharing for such a service in May, of the same plan year.

To reconcile the obligations of complying with coverage and notice requirements, the Chamber respectfully recommends that changes to guidelines be made only once a year. The addition of new guidelines and the removal of prior guidelines should be done at a specific time period once a year to provide certainty and continuity for plans. We recommend that

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<sup>11</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,728-9. “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.”

<sup>12</sup> URAC American Accreditation HealthCare Commission, *Trends and Practices in Medical Management*, at 6 (2002) (available at: <http://www.urac.org/docs/resources/MMReport2001.pdf>).

<sup>13</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,729. “Therefore, by visiting this site once per year, plans or issuers will have straightforward access to all the information necessary to determine any additional items or services that must be covered without cost-sharing requirements, or to determine any items or services that are no longer required to be covered.”

<sup>14</sup> Id.

<sup>15</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,758 (to be codified at 29 CFR §2590.715-2713 (b)(2)).

<sup>16</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,758 (to be codified at 29 CFR §2590.715-2713 (b)(2)).

changes be announced in February of each year to permit plans that the appropriate time to provide advance notice and comply with these changes for plan years beginning on or after June 1<sup>st</sup> of that same year.

3. Distinguishing Recommended Treatment from Required Preventive Service  
Treatment resulting from a preventive screening can be subject to cost sharing requirements if the treatment is not itself a recommended preventive service.<sup>17</sup> The guidelines delineated in the regulations often make mention of appropriate treatment that should be recommended. For example, the U.S. Preventive Services Task Force “recommends that clinicians screen children aged 6 years and older for obesity and *offer* them *or refer* them to comprehensive, intensive behavioral interventions to promote improvement in weight status.”<sup>18</sup> The regulations need to clarify that for guidelines where treatment is discussed, plans are neither required to provide that treatment nor to waive cost sharing requirements for that treatment.
4. Synchronizing Regulations with Current Tax Provisions  
A number of the preventive service guidelines refer to over-the-counter medicine or items. “The U.S. Preventive Services Task Force recommends the use of aspirin for men age 45 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm for an increase in gastrointestinal hemorrhage.”<sup>19</sup> It is inconsistent that the same law which will now prevent the use of tax preferred dollars to purchase over-the-counter drugs<sup>20</sup> would also require plans and employers to pay for them as a medical expense. The regulations need to clarify that although the use of over-the-counter medicine is recommended, plans are not required to pay for such items on a tax preferred basis.
5. Future Guidelines  
The preamble states that [t]he Department of HHS is developing additional guidelines on evidence-informed preventive care and screening [for women which will be] provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force) to be issued no later than August 1, 2011.<sup>21</sup> The Chamber respectfully requests that, when such guidance is issued, notice and an opportunity for public comment be provided.

## **COMMENTS SOLICITED**

The Departments requested comments on the development of additional guidelines regarding the utilization of value based insurance designs that promote consumer choice of provider and services that offer the best value and quality while ensuring access to critical, evidence-based preventive services.

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<sup>17</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,728 and 41,758 (to be codified at 29 C.F.R. §2590.715-2713 (a)(2)(iv) example 2.

<sup>18</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,743 (with emphasis added).

<sup>19</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,741.

<sup>20</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 9003, 124 Stat. 119 (2010). “Reimbursement for expenses incurred for a medicine or a drug shall be treated as a reimbursement for medical expenses only if such medicine or drug is a prescribed drug or is insulin.”

<sup>21</sup> Preventive Service Coverage, 75 Fed. Reg. at 41,728

Employers are currently implementing programs that reduce barriers to access of, as well as the cost for, selective medications that are instrumental in managing chronic health conditions, such as diabetes, asthma, and hypertension.<sup>22</sup>

This regulation does not specifically address the need for value-based pharmacy design for selected chronic health conditions per se (except for the prescription of aspirin, and tobacco cessation therapies). However, in response to inquiries on the utilization of value-based insurance designs by group health plans and health insurance issuers for preventive benefits, the Chamber recommends that the Departments permit variations in co-pays or co-insurance for medication therapies when designated pharmacies or pharmacy benefits managers are utilized. Additionally, employers have been at the forefront of developing “high performing networks,” or health plans which designated a special category within the provider network for “high performing providers.” In these plans, enrollees cost sharing obligations vary based on the quality of the practitioner providing care. The Chamber, as representative of the employer community, requests that the forthcoming guidance document encourage plan sponsors to vary cost sharing obligations for plan enrollees who opt to select practitioners that are deemed to be of “high quality”, and are in a specified “high performing” provider network, if preventive services are provided in an office visit.

## **CONCLUSION**

We appreciate the opportunity to comment on the IFRs and are available to discuss any of our comments informally, or by way of testimony in hearings conducted by the Departments. While we support the general principles of expanding coverage and improving access to preventive services, we are concerned by some critical elements of the Interim Final Rules implementing the coverage of preventive services provisions. We hope that with our comments and examples, the Departments will make the necessary changes, as we have suggested, to improve this interim final regulation. We look forward to working with you to protect the fundamental goals of health reform that we jointly support.

Sincerely,



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<sup>22</sup> U.S. Chamber of Commerce and Partnership for Prevention: “Healthy Workforce 2010 and Beyond: An Essential Health Promotion Sourcebook for Both Large and Small Employers”, p. 39,  
(<http://www.prevent.org/data/files/topics/healthyworkforce2010andbeyond.pdf>)