

September 17, 2010

Office of Consumer Information and Insurance Oversight  
Department of Health and Human Services  
Attention: OCIO-9992-IFC  
PO Box 8016  
Baltimore, MD 21244

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

Internal Revenue Service  
CC: PA: LPD: PR, (REG-120391-10)  
Room 5025  
P.O. Box 7604 Ben Franklin Station  
Washington, DC 20044  
Attention: REG 120391-10

**RE: File Code OCIO-9992-IFC/RIN 1210-AB44/REG-120391-10, 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 Secretary Sebelius, Deputy Commissioner Miller, Assistant Secretary Borzi, Assistant Secretary Mundaca and Director Angoff:

The undersigned organizations, representing millions of consumers and patients, thank you for the opportunity to comment on the Interim Final Rules pertaining to coverage of preventive screenings and services<sup>1</sup> under the Patient Protection and Affordable Care Act (“Affordable Care Act” or ACA).<sup>2</sup> Coverage of preventive services – at no cost-sharing to the consumer - represents an important commitment to, and investment in, keeping people healthy rather than simply treating them once they have become sicker and costlier patients. Indeed, it is a critical component of the new health care law.

Many of our comments regarding the Interim Final Rules relate to coverage of services recommended by the U.S. Preventive Services Task Force (USPSTF). As you may well know, the USPSTF recommendations were written with the purpose of “assessing the merits of

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<sup>1</sup> 75 Fed. Reg. 41726 (July 19, 2010).

<sup>2</sup> Pub. L. No. 111-148 (2010), as amended by the Health Care and Education Affordability Reconciliation Act, Pub. L. No. 111-152 (2010).

preventive measures,”<sup>3</sup> not establishing policy regarding whether health plans should cover preventive services without cost-sharing. Accordingly, the structure and language of the recommendations are not always clear or uniform. In many cases, the USPSTF might present evidence or cite other organizations’ recommendations relating to frequency or method without making a well defined recommendation themselves. We certainly appreciate the difficulty of establishing policy based on these recommendations, but this difficulty only exemplifies the urgent need for clear and specific implementing regulations. We offer the following comments to further strengthen and clarify these important rules.

**1. The Summary Chart: The summary chart of recommended preventive screenings provided should be identified as provided for convenience – not as the ultimate source of information – and final regulations should reference the full USPSTF recommendations as the authoritative source.**

The Affordable Care Act requires non-grandfathered health plans to cover preventive services and screenings recommended by the USPSTF with a grade “A” or “B” without cost-sharing. The Preamble to the Interim Final Rules includes a summary table containing the 45 preventive services and screenings recommended by the USPSTF.<sup>4</sup> We appreciate the desire to include an easy-to-follow chart that reflects the recommendations of the USPSTF, but are concerned that the chart does not reflect the full recommendations as to frequency, nor the definition of high risk populations where indicated. Any summary chart should reflect the full recommendations of the USPSTF to include frequency and/or high risk populations.

a. *Frequency of recommended screenings*: There are several screenings listed in the summary chart where a recommended frequency is not identified – yet the full recommendation of the USPSTF does include a recommended frequency. For example, screening for cervical cancer is recommended by the USPSTF; the summary chart does not include a recommended frequency,<sup>5</sup> but the full USPSTF recommendation does. Another example is the screening for colon cancer – where the summary table does not include a recommended frequency, but the full USPSTF recommendation does include a recommended frequency.

b. *Definition of High-Risk Population*: Within the summary chart, there is a similar issue for the definition of a high risk population. Some of the recommended screenings listed in the chart are identified for high risk populations - but this is not defined in the summary chart, rather, it is defined in the full recommendation. For example, the summary chart identifies that women at high risk for breast cancer receive genetic counseling for the BRCA gene and chemoprevention of breast cancer, but the chart does not define “high risk.” The USPSTF full recommendation does, however, specify what is considered to be “high risk.” Where a screening or service is recommended for someone who is at high risk, the summary chart should either identify who is at high risk, or refer to the full recommendations.

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<sup>3</sup> US Preventive Services Task Force, “USPSTF Recommendations,” [www.uspreventiveservicestaskforce.org/uspsttopics.htm](http://www.uspreventiveservicestaskforce.org/uspsttopics.htm)

<sup>4</sup> 75 Fed. Reg. at 41741-44.

<sup>5</sup> *Id.* at 41741.

## **2. Where USPSTF Is Silent As To Frequency Of Screenings: The final regulations should provide a clear definition of “reasonable medical management techniques.”**

Where the USPSTF recommendations are silent as to frequency, the Interim Final Rules allow health plans to set limits based on “reasonable medical management techniques.” However, the Interim Rules do not define this term, nor is this a term for which we could find any commonly accepted definition. We are concerned with the notion of providing health plans the ability to exercise such discretion without any oversight or appeal rights. Furthermore, there could be significant and understandable consumer confusion as different plans may reach different conclusions about “reasonable medical management techniques.” To fully protect consumers and to avoid any confusion, we urge that the final regulations reflect the following recommendations.

- **Clear definition:** The final regulations should clearly define “reasonable medical management techniques.”
- **Use and identify source:** Health plans should use and publicly identify a credible reference or source in making determinations of reasonable medical management techniques.<sup>6</sup>
- **Recourse:** Health plan enrollees should have the right to appeal determinations made by health plans as to frequency of preventive services. These appeal rights should be both internal as well as external.
- **Agency oversight:** The Departments should exercise adequate oversight over health plan determination of frequency.

## **3. Where the recommended frequency is unclear or ambiguous: The final regulations should address and clarify coverage of no-cost preventive services and screenings where the recommendations are unclear or ambiguous.**

In several cases, the USPSTF provides unclear or ambiguous recommendations as to frequency of a recommended service or screening. We are concerned that, absent clarification, plans will exercise discretion as to whether to cover these screenings without cost-sharing. One example of an ambiguity is in regards to cervical cancer screenings. The USPSTF recommendation summary states that, “Indirect evidence suggests most of the benefit can be obtained by...screening at least every 3 years.”<sup>7</sup> This is further explained in the full Recommendation and Rationale Statement; “The USPSTF found no direct evidence that annual screening achieves better outcomes than screening every 3 years.”<sup>8</sup> However, adding to the ambiguity, the statement goes on to suggest that for some women, annual screenings may be necessary, stating that, “most organizations in the United States recommend that annual Pap smears be performed until a specified number (usually two or three) are cytologically normal before lengthening the screening interval” and further continues that, “the American College of Obstetricians and Gynecologists (ACOG) identifies additional risk factors that might justify annual screening.”<sup>9</sup>

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<sup>6</sup> For example, plans could refer to the Millman Care Guidelines: [www.careguidelines.com](http://www.careguidelines.com).

<sup>7</sup> The U.S. Preventive Services Task Force, “Screening for Cervical Cancer: Recommendation and Rationale,” <http://www.uspreventiveservicestaskforce.org/3rduspstf/cervcan/cervcanrr.htm>

<sup>8</sup> *Id.*

<sup>9</sup> The U.S. Preventive Services Task Force, “Screening for Cervical Cancer: Recommendation and Rationale,” <http://www.uspreventiveservicestaskforce.org/3rduspstf/cervcan/cervcanrr.htm> (citing the American College of Obstetricians and Gynecologists).

Certainly, if a woman presents with additional risk factors that her doctor would recommend an annual screening, she should be eligible for that screening at no-cost. But this is just one example of such an ambiguity. The final regulations should clarify that in those cases where the USPSTF recommendation is ambiguous as to frequency, the recommendation of the physician should prevail.

4. **High Risk Populations: The final regulations should address frequency of screenings for high risk populations where the USPSTF is silent.**

Some USPSTF recommendations address screenings for high risk populations, others do not. Clearly, there will be times when in treating someone at high risk, it is within the standard of care for a health care provider to recommend a screening or preventive service more frequently than the recommendations of the USPSTF. In the case where the USPSTF recommendation is silent as to a recommendation for high-risk populations, and a health care provider recommends more frequent screenings than the USPSTF for a high-risk patient, the health care provider recommendation should trump the health plan in such circumstances and the individual should be eligible for no-cost screenings. One such example could be a woman under age 40, with a direct and close family history of early onset breast cancer, and her doctor recommends annual mammograms. Because the doctor has recommended the screening due to her high risk, that patient should receive those screenings with no additional cost-sharing.

For patients with certain chronic conditions, screenings are used as a form of disease monitoring, but for others with chronic conditions who are at higher risk for certain preventable conditions, screenings are a crucial prevention tool. The final regulations should clarify and distinguish the two types of screenings for patients with chronic conditions: screenings that are used as a form of disease monitoring would not be eligible for no-cost-sharing, however, the latter should be, consistent with our recommendation for high risk populations as provided above.

5. **Form of Screening: The final regulations should address where the USPSTF recommendation is silent as to the form of the recommended screening or service.**

Many of the USPSTF recommendations are silent as to a form or method of a recommended screening. We are concerned that where the USPSTF recommendations are silent, health plans might only cover at no cost one particular type of screening or service versus another—particularly where there is a cost difference. For example, the USPSTF recommends screenings for cervical cancer but does not specify the type. There are currently several FDA approved types of pap tests that include the conventional pap smear, and newer tests such as the “Thin Prep.” Without clarification, plans might only cover the conventional test without cost-sharing, while still imposing cost-sharing for other tests. Similarly, where the USPSTF recommends “counseling” but the recommendation is silent as to the form, plans may only cover and/or provide no cost-sharing for recorded telephone messages versus face-to-face counseling. The Final Regulations should clarify and address such ambiguities. This clarification is especially important as patients often have no choice as to the specific screening test used by their health care provider – these patients should not be shut out from this important protection.

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**6. Services “Not Recommended” by the USPSTF: Final regulations should clarify that screenings “not recommended” by the USPSTF refers to those services receiving grade “D” from the USPSTF.**

The statute provides, and the regulations reflect, that plans are allowed to deny coverage for services that are “not recommended” by the Task Force – but this is not defined. We are concerned that this would inadvertently give plans express permission to deny coverage altogether for screenings that are simply not addressed by the USPSTF - let alone at no-cost. The final regulations should be clarified to state that “not recommended” by the USPSTF means those services receiving a “grade D” from the Task Force. Services receiving a grade D, by definition, means “The USPSTF recommends against the service.”

**7. Value Based Insurance Design: The Secretary of HHS should clearly define value based insurance design to avoid potentially broad and unfair interpretation by insurance companies and health plans.**

The ACA gives the Secretary of Health and Human Services the authority to create guidelines for use of value-based insurance design (VBID) in the provision of preventive services.<sup>10</sup> VBID is meant to increase value of health care provided through insurance.<sup>11</sup> Regulations defining VBID should make it clear that the program must be aimed at improving health outcomes and increasing quality of care. A program that aims to reduce costs by limiting medically necessary services or access is not a value-based program.

The following are key provisions we believe are necessary in consideration of regulations defining allowable VBID programs:

- The key principle of value-based design is high quality, more efficient care. Therefore, any allowable use of VBID should include rigorous performance measures to ensure that plans are not simply using this model to reduce costs, but are actually linking costs to quality as a way to produce value. Performance measures should be publicly reported. HHS should evaluate VBID implementation annually to assess its impact on access to care and publicly report these findings.
- CMS should consider providing guidance that ensures that plans address subpopulation differences in identifying, in particular, which services and treatments get preferred "high value" recognition so that VBID helps to close rather than exacerbate health disparities.

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<sup>10</sup> Section 2713(c) of the Pub. Health Serv. Act, as added by the Affordable Care Act, Pub. L. No. 111-148 (2010).

<sup>11</sup> A. Mark Fendrick, MD; et al. “Value-Based Insurance Design: Embracing Value Over Cost Alone,” 15 Am. J. of Managed Care at S278 (Dec. 2009). (“Instead of focusing on cost or even quality, VBID focuses on *value*, aligning the financial and nonfinancial incentives of the various stakeholders and complementing other current initiatives to improve quality and subdue costs...The overarching goal of VBID is better population health rather than saving money.”)

- VBID programs should meet anti-discrimination requirements<sup>12</sup> and recognize cultural, linguistic, and economic realities of individuals. The program should be accessible by plan participants who do not speak English and should be provided in a format that is easily understood by the participants. A VBID program that requires individuals to take time off work to fulfill key aspects of the program should not be allowed in an employer sponsored plan unless the employer provides paid sick leave.
- VBID should be used to promote – not limit - access to recommended preventive services. For example, a plan should not be allowed to only provide free preventive care to participants who participate in a disease management or wellness program.
- VBID should not limit the network to a point in which individuals cannot access free preventive service. For example, a plan should not be allowed to limit free preventive care to certain in-network providers who charge less for the services without any consideration for quality of service.
- It should be made clear that designation as a VBID does not, by itself, exempt plans from complying with other requirements in the ACA and associated regulations. For example, a small group plan should not be allowed to institute a higher deductible than allowed by the ACA for individuals who do not meet certain requirements or do not participate in a VBID program.

**8. Women’s preventive services: We urge development of a more timely process to ensure no-cost-sharing coverage of recommended women’s preventive services under the Women’s Health Amendment, and a process to regularly update the recommended services and screenings.**

Section 2713(a)(4) of the Public Health Service Act, known as the Women’s Health Amendment to the ACA, requires the Health Resources and Services Administration (HRSA) to identify preventive health services for women, in addition to those recommended by the USPSTF, that should be covered and protected from cost-sharing in all new health insurance plans. This important amendment—the first offered during the Senate debate—was intended to supplement other key provisions in the bill and ensure coverage of and cost-sharing protections for family planning services,<sup>13</sup> annual well-woman visits,<sup>14</sup> screening for intimate partner and family violence,<sup>15</sup> and other preventive health services that are currently not among those recommended by the USPSTF. We fully expect that any process used to develop women’s health guidelines

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<sup>12</sup> See section 1557 of the Affordable Care Act, Pub. L. No. 111-148 (2010).

<sup>13</sup> S12025 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Boxer); S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Gillibrand); S12028 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Mikulski); H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Feinstein).

<sup>14</sup> S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Shaheen); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin).

<sup>15</sup> S12025 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Boxer), ); S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Gillibrand); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin).

will be guided by scientific evidence, will reflect public health consensus and Congressional intent, and will result in coverage of these services.

Furthermore, while we appreciate that the Interim Final Rule establishes a timeline for the development of guidelines, we are concerned that given that timeline, most plans will not be required to comply until January 2013. Accordingly, we urge the Department to develop a more timely process for identifying additional women's preventive health services to be covered and for plan compliance.

Finally, we urge the Department, in implementing the Women's Health Amendment, to identify a mechanism for regularly updating these guidelines in order to ensure that they reflect new technologies and new evidence.

9. **Primary Purpose Test/Separate Billing: Final regulations should be strengthened such that a consumer could understand when they are responsible for cost-sharing for a preventive screening or service provided with other health care services.**

To address the issue of cost-sharing when a preventive screening or service is provided as part of an office visit that includes other services, the Interim Final Rules adopt a "primary purpose" and separate billing test. From a consumer perspective, the standard is simply not workable. At best, this would leave consumers without any clear understanding of when they would be responsible for any cost-sharing. At worst, this could leave a consumer subject to billing games between their health care provider and their insurer. Furthermore, it is not unreasonable to think that a consumer would be stuck paying the cost-sharing at the provider's office until the provider and the insurer work out whether the visit is subject to no co-payment. Accordingly, the final regulations should further clarify this rule from the perspective of the consumer: i.e., under the rule, a consumer should be able to clearly determine if or when they would be responsible for any cost-sharing for a preventive screening or service.

10. **Cost-sharing for Preventive Services Provided Out-of-Network: Final regulations should clarify that cost-sharing for preventive services provided out-of-network may not be higher than any other service provided out-of-network.**

The Interim Final Rules provide that screenings/services provided out-of-network are subject to cost-sharing. However, final regulations should clarify that cost-sharing for out-of-network screenings should not be any higher than for any other health care services provided out-of-network.

11. **Notice to plan enrollees: Plans should be required to provide adequate notice to enrollees of coverage of preventive services and screenings.**

Coverage of preventive services is an important new protection for many plan enrollees. Accordingly, clear notice should be provided to plan enrollees about no cost-sharing for recommended preventive screenings and services. To ensure standardization, HHS and DOL should provide a form for plans to use. This information should be available in multiple

languages for individuals with limited English proficiency and other formats for visually and hearing impaired consumers.<sup>16</sup>

**12. Enforcement: Final Regulations should provide enforcement and oversight of plans regarding coverage of preventive screenings and services.**

The Interim Final Rules are silent as to enforcement/oversight of plans. Final regulations should clearly address this issue- including specific appeal rights. Furthermore, the regulations should provide for the Departments (HHS and DOL) to exercise oversight over plan compliance with these regulations.

**Conclusion**

We thank you again for the opportunity to comment on these important regulations to ensure coverage of preventive services; the recommendations we offer above will further clarify these protections and help to minimize potential consumer confusion regarding those preventive services eligible for no cost-sharing. We look forward to working with you in the future as you continue to implement the Affordable Care Act.

Sincerely,

American Federation of State, County and Municipal Employees (AFSCME)  
Bluewave NJ  
Campaign for Community Change  
Community Catalyst  
Families USA  
Health Access California  
NARAL Pro-Choice America  
National Partnership for Women and Families  
The National Multiple Sclerosis Society  
National Women's Law Center  
Service Employees International Union (SEIU)  
Young Invincibles

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<sup>16</sup> See section 1557 of the Affordable Care Act, Pub. L. No. 111-148 (2010).