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BlueCross BlueShield Association

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Blue Cross and Blue Shield Plans

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Jay Angoff
Director, Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services

The Honorable Phyllis C. Borzi
Assistant Secretary, Employee Benefits Security Administration
U.S. Department of Labor

The Honorable Michael F. Mundaca
Assistant Secretary of the Treasury
U.S. Department of the Treasury

Submitted via the Federal Rulemaking Portal: http://www.regulations.gov

Re: Comments on Interim Final Rule Related to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (OCIIO-9992-IFC)

Dear Director Angoff and Secretaries Borzi and Mundaca:

The Blue Cross and Blue Shield Association ("BCBSA") – representing the 39 independent Blue Cross and Blue Shield Plans ("Plans") that collectively provide health coverage to nearly 100 million, or one in three Americans – appreciates the opportunity to submit comments on the Interim Final Rules (the "Rule") for Group Health Plans and Health Insurance Issuers ("plans") Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act ("ACA") as issued in the *Federal Register* on July 19, 2010 (75 Fed. Reg. 41726).

BCBSA commends the Departments for striking a fair and reasonable balance between ensuring access to preventive services and ensuring that group health plans and health insurance issuers remain able to manage these new requirements in a reasonable manner. By permitting, for example, cost-sharing for recommended preventive services delivered on an out-of-network basis, use of reasonable medical management techniques to determine the frequency, method, treatment, or setting for certain recommended items and services, and cost-sharing for office visits when a recommended preventive service is billed separately, the Rule will help plans and issuers limit impacts on premiums.

While the rule itself is fair and reasonable, we believe it does not address an inherent "structural" problem: the various recommendations for preventive services were written for

guidance to clinicians on providing clinical services, they were not issued in the context of health care coverage determinations.

Section 2713 provides that "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage" cover as benefits recommendations of (1) the United States Preventive Services Task Force (Task Force) that have in effect a rating of ‘A’ or ‘B’; (2) immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control; (3) preventive care and screening for infants, children, and adolescents supported by the Health Resources and Services Administration (HRSA); and (4) additional preventive services for women [guidelines to be developed].

Because these recommendations, developed by panels of clinicians for use by other clinicians, were never intended to be used for coverage purposes, they lack the precision of standards developed expressly for the purpose of providing coverage of health care services. And having been developed by different panels of experts over many years, the language contained in the recommendations is not always consistent.

Therefore, many of the Task Force recommendations contain ambiguities that could lead to varying interpretations. Moreover, because the current sets of ICD-9-CM and CPT codes have limitations that make it challenging to recognize the covered preventive services in each and every claim, different organizations may develop different coding algorithms to identify covered services within claims for adjudication, leading possibly to variations in coverage determinations.

In light of these ambiguities and uncertainties, BCBSA respectfully requests that:

(1) The Departments issue guidance to clarify that the Departments will take into account good faith efforts to comply with reasonable interpretations of the statutory requirements: this would include good faith efforts to interpret the preventive service recommendations – at least until such time as the Departments issue the subregulatory guidance requested under (2). Allowing such good faith efforts would be consistent with the interim final regulations relating to preexisting condition exclusions and lifetime and annual limits on benefits, which recognize that plans and issuers should not be sanctioned when the terms underlying a rule are vague or ambiguous or undefined.

(2) The Departments issue subregulatory guidance defining each recommendation more precisely by providing guidance on options for coding to make benefit determinations. If the Departments are unable to provide a clear understanding on how to code a benefit, then coverage of that benefit should be pended until the appropriate codes become available. Options for coding would include indicating which recommendations should be provided during comprehensive preventive medical visits.

In addition to this overarching request for a good faith standard and for help in mitigating ambiguities, BCBSA would like to submit the following requests for specific clarifications – some relating to the recommendations, others to the Rule itself – that the Departments may wish to issue in subregulatory guidance.

I. BRCA Screening

Issue. The Task Force recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing. This language, and the associated clinical considerations in the recommendation statement, seems clearly to draw the line before actual testing, although, as discussed below, there is ambiguity whether plans must cover the referral only, or the genetic counseling and evaluation. However, the preamble refers to "recommendations for testing for the BRCA gene." This language substantially expands the Task Force's definition.

While genetic testing does not fall within the scope of the recommendation, the language does contain some ambiguity regarding what exactly is to be covered: is it (1) the referral for genetic counseling and evaluation; or (2) the referral *and* the genetic counseling and evaluation. On the one hand, the recommendation states that: "[W]omen with certain family history patterns. . . would benefit from genetic counseling that allows informed decision-making about further testing and prophylactic treatment. This counseling should be done by suitably trained health professionals." This language would seem to imply that compliance with the Task Force recommendation requires covering counseling and evaluation, at least for eligible patients.

On the other hand, the recommendation also states: "Although there currently are no standardized referral criteria, women with an increased-risk family history should be considered for genetic counseling to further evaluate their potential risks." This language would seem to imply that the focus of the recommendation is on the decision to refer. When combined with the plain words of the recommendation, that at-risk women "*be referred* [emphasis added] for genetic counseling and evaluation," we believe that the most accurate interpretation of the Task Force's recommendation is to cover only the decision to refer.

Recommendation: To avoid any ambiguity, BCBSA requests that the Departments clarify that under the Task Force recommendation regarding BRCA screening, plans are not required to cover genetic testing. Further, BCBSA requests that the Departments clarify that plans are required to cover an office visit/consultation for a woman's need for genetic counseling and the physician's referral for counseling and evaluation. We would presume, consistent with the Rule's provision regarding treatments that are not part of the preventive services recommendation, that plans may impose cost-sharing requirements for any subsequent genetic counseling or evaluation resulting from the referral that is a covered preventive service.

II. Screening for Obesity in Adults

Issue. The Task Force recommends that clinicians screen all adult patients for obesity and *offer* [emphasis added] intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Since "offer" means "to present for acceptance or rejection," BCBSA believes that the recommendation covers "screening and offering," and not the intensive counseling and behavioral interventions that might result from the screening and offering.[1]

[1] http://www.merriam-webster.com/dictionary/offer

However, because the clinical considerations section of the recommendation statement talks about "the most effective interventions" and defines high-intensity interventions, the Task Force recommendation could be construed (incorrectly in our view) to cover intensive counseling and behavioral interventions.

***Recommendation*:** BCBSA requests that the Departments clarify that under the Task Force recommendation on screening for obesity in adults, plans would not be required to cover with no cost sharing intensive counseling or behavioral interventions for obesity patients that a physician recommends, following a screening, to his or her patients.

III. Coverage for Aspirin

Issue. The Task Force has made two recommendations that address use of aspirin. From the "Summary of Recommendations" on the Task Force's web site:

- The Task Force recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.

- The Task Force recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.

Ambiguities in the wording of the recommendations – and wording in the preamble – raise uncertainties whether plans would need to cover aspirin or simply physicians' advice to use aspirin.

Although the summary of the recommendation recommends "use of aspirin," the recommendation in the "Clinical Guidelines" section of the Recommendation Statement published in the *Annals of Internal Medicine* (March 2009) is: "Encourage men age 45 to 79 years to use aspirin . . . [and] Encourage women age 55 to 79 years to use aspirin." This wording is consistent with the preamble's reference to this recommended preventive service as "discussing aspirin use with high-risk adults" (75 Fed. Reg. 41735).

***Recommendation*:** BCBSA requests that the Departments clarify that the Task Force recommendation relating to aspirin is a directive to physicians to counsel their patients on the benefits of taking aspirin; therefore, plans must cover such counseling as a recommended preventive service, and not cover aspirin, which is readily available over-the-counter, and would not be covered under ACA-required essential benefits that include prescription drugs but not over-the-counter drugs.

IV. Coverage of Immunizations for Travelers

Issue. The recommended adult immunization schedule shows that five routine vaccinations are indicated for international travelers. However, each vaccination recommendation uses a different criterion for applying this travel indication:

- Varicella: International travelers at high risk for exposure or transmission.

- 2nd dose of MMR: Persons who plan to travel internationally.

- Hepatitis A: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (CDC lists countries).

- Hepatitis B: international travelers to countries with high or intermediate prevalence of chronic HBV infection (CDC lists countries).

- Meningococcal: Persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December through June]), particularly if their contact with local populations will be prolonged.) The schedule also notes that: "vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the Haj."

The inconsistencies and ambiguities in these criteria could lead to varying and inconsistent coverage determinations across organizations and across persons traveling internationally. Moreover, plans currently have no way of knowing that a claim for a vaccination was for international travel, unless plans were to establish a pre-authorization process for those vaccinations.

***Recommendation*:** BCBSA requests that HHS task the Advisory Committee on Immunization Practices (ACIP) with clarifying and standardizing, to the extent appropriate, the language used to indicate vaccinations associated with international travel. In addition, BCBSA requests that HHS clarify that plans may establish pre-authorization procedures to determine whether an enrollee qualifies for a vaccination as an international traveler (or other specified eligible sub-populations, such as health care personnel – see section VI).

V. <u>Tobacco Cessation Interventions</u>

***Issue*.** The Task Force recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Although the clinical considerations section of the recommendation discusses various interventions – counseling, motivational interviewing, nicotine replacement therapy (gum, lozenge, transdermal patch, inhaler, and nasal spray), sustained-release bupropion, varenicline, and combination therapies – it is very difficult to translate these into coverage determinations because, as the Task Force notes, "clinical or policy decision involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision-making to the specific patient or situation."

Without guidance on specific risk factors for making a reasonable coverage determination, Plans are concerned about processing claims for tobacco cessation interventions. Such uncertainty may have a chilling effect on Plans' ability to support beneficial or innovative approaches to treatment.

***Recommendation*:** BCBSA requests that HHS provide guidance on what would be reasonable determinants for different treatment approaches. For example, HHS could clarify that if plans were to, at a minimum, follow Medicare policy, then they would be in compliance. Medicare's new Medicare Smoking Cessation Program will cover up to eight face-to-face visits during a 12-month period for people who are diagnosed with a smoking-related illness (e.g., heart disease, cerebrovascular disease (stroke), multiple cancers, lung disease, weak bones, blood clots, and cataracts) or are taking medicine whose effectiveness is complicated by tobacco use (e.g., insulin). However, nothing would prevent

a plan from going further than Medicare and covering tobacco cessation for those who do not have a smoking-related illness.

In addition, BCBSA requests that the Departments clarify that in applying reasonable medical management techniques, nothing would preclude a plan from choosing to cover, with no cost sharing, screening and counseling, and to cover with cost sharing (or not to cover) pharmacotherapy in general or specific types of pharmacotherapy.

VI. Health Care Personnel

Issue. The recommended adult immunization schedule shows that various routine vaccinations are indicated for health care personnel. However, it is not uncommon for health care employers to provide – or to be required to provide – certain vaccinations to their employees. For example, OSHA Bloodborne Pathogen standard 1910.1030 states: "the employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposures... at no cost to the employee, ...at a reasonable time and place, and ...according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place." Although ACA does not preempt the OSHA standard, nothing would prevent an employer from giving bills to its health care employees to submit to their health plan to shift financial responsibility – and, as in the case for international travelers, plans would have no way of knowing that a claim for an immunization was for a health care professional.

***Recommendation*:** BCBSA requests that the Departments clarify that where an employer already provides vaccinations or any other preventive services free of charge to its health care personnel, then plans will not be responsible for covering these services.

VII. Hospital-only Policies

Issue. ACA does not specifically limit the application of Section 2713 to particular types of products, other than “excepted benefits”. It appears that neither Section 2713 nor the Rule contemplated a scenario where an insurer provides hospital-only coverage, which raises potentially significant problems for “hospital-only” plans or policies offered in the group and individual markets.

These products generally cover hospital in-patient, out-patient, surgery, and associated services; they do not cover medications or office visits. They may cover some preventive services available through hospital outpatient departments, such as mammography screenings.

Individuals and groups who have hospital-only policies may have no other coverage – hospital plans tend to be among the lowest priced plans and appeal to those facing financial hardships – or they may have a separate medical policy, issued by a different insurer, that covers items and services offered outside the hospital

Requiring a hospital-only plan to cover preventive services rendered in a physician’s office could stop insurers from offering such plans because (1) insurers would have to engage in costly re-contracting with providers because the insurer likely would not have network providers contracted in a way that obligates the providers to render professional medical services to members covered under hospital-only polices; and (2) providing coverage for

preventive office visits may trigger application of benefit mandates under state law that are based on physician office visits, such as chiropractic care, thus raising the cost of the product out of reach of current purchasers.

In addition, if the hospital-only plan is coupled with a medical policy offered by a different issuer, requiring both to cover the recommended preventive services could lead to primacy questions and confusion for consumers.

Recommendation: BCBSA requests that the Departments issue two clarifications regarding hospital-only plans:

- First, when the hospital-only plan/policy is held by a group/individual that also has a plan/policy offered by a separate issuer that covers other items and services (e.g., professional fees and medications), then the Rule should apply to the "group health plan" as a whole, and the group/individuals should be responsible for coordinating the plan/policy to avoid primacy questions and consumer confusion.

- Second, when the hospital-only plan/policy is the only coverage held, or where the issuer cannot confirm that this policy is the only coverage held, then the Rule would require coverage of preventive services to the extent they represent hospital-based preventive services, including outpatient facility preventive screenings such as colonoscopies and mammograms. Consistent with the ability to use reasonable medical management techniques to determine the setting for an item or service, such a hospital-only plan/policy would not be required to cover preventive services customarily provided by a physician or other practitioner in an office or other non-facility setting.

Further, BCBSA requests that the Departments apply the logic of these clarifications to analogous situations for other types of plans/policies, as when a plan or policy only provides medical coverage, not drug coverage

VIII. Task Force

Issue. Over the years the Task Force has done exemplary work, and even though ACA creates a new use for the Task Force recommendations, nothing should change that would interfere with the Task Force being considered the "gold standard" for recommendations on clinical preventive services: it should remain an "independent panel of non-Federal experts." However, in light of Section 2713, it seems only prudent for the Task Force to recognize the added import of its recommendations.

The current mission of the Task Force includes making recommendations about which preventive services should be incorporated routinely into primary medical care and for which populations:

1) Assess the benefits and harms of preventive services in people asymptomatic for the target condition, based on age, gender, and risk factors for disease.

2) Make recommendations about which preventive services should be incorporated routinely into primary care practice.[2]

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[2] U.S. Preventive Services Task Force Procedure Manual. AHRQ Publication No. 08-05118-EF, July 2008. http://www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual.htm

As noted earlier, because they were written for guidance to clinicians and not for health care coverage determinations, the current Task Force recommendations have proven difficult to convert into coverage policies.

Recommendation: BCBSA recommends that the Department of Health and Human Services work with the Task Force to harmonize the Task Force's current essential mission with the new use of its recommendations under ACA. This could include adding a third objective to the Task Force's mission: To the extent practicable, structure recommendations about preventive services so that health plans can accurately implement them.

For example, in future recommendations, the Task Force might be more specific in its recommendations: which interventions, which patients, how often, etc. If the Task Force were to recommend service for only a subset of patients, what age groups or patient risk factors should apply? It would also be helpful for the Task Force to indicate whether it envisions that a recommended preventive service should be part of a comprehensive preventive medicine visit (either as counseling, risk factor reduction, or part of the examination).

These recommendations should also apply to other entities that the government forms to make recommendations that will become benefit mandates under Section 2713.

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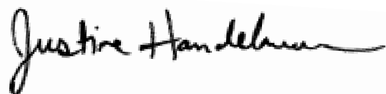
We appreciate your consideration of our comments on the Rule and thank you for considering our suggested recommendations and requests for clarifications. We look forward to continuing to work with the Departments on implementation issues related to ACA. If you have any questions, please contact Joel Slackman at Joel.Slackman@bcbsa.com or 202.626.8614.

Sincerely,



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