



September 17, 2010

U.S. Department of Labor
Employee Benefits Security Administration
Office of Health Plan Standards and Compliance Assistance
Attention: RIN 1210-AB44
Room N-5653
200 Constitution Avenue, NW
Washington, D.C. 20210

U.S. Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Attention: OCIO-9992-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

Internal Revenue Service
Attention: CC:PA:LPD:PR (REG-120391-10)
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Interim Final Regulations for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (RIN 1210-AB44; OCIO-9992-IFC; REG-120391-10)

Submitted via the Federal eRulemaking Portal at: <http://www.regulations.gov>

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to offer comments in response to the interim final regulations for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act ("Affordable Care Act").¹ The interim final regulations were published in the *Federal Register* on July 19, 2010 (75 Fed. Reg. 41726).

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of

¹ Pub. L. No. 111-148, as amended by Pub. L. No. 111-152.



health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

We commend the agencies for issuing regulatory requirements that proactively place the health care needs of Americans at the forefront of priorities under the Affordable Care Act. Health insurance plans have a long history and proven record of offering preventive services to individuals to improve their health and care. AHIP members appreciate the recognition noted in the preamble and the regulations that many plans and issuers currently cover recommended preventive services and, in some cases, provide coverage for preventive services that go beyond those required by the Affordable Care Act.² We support the agencies' efforts and reaffirm our commitment to consumers by continuing to support evidence-based preventive services to help reduce the onset or severity of illness or disease.

Our review of the interim final regulations noted the inclusion of several important principles (e.g. coverage of evidence-based items/services; use of medical management; "primary purpose" of an office visit). We encourage the agencies to retain these provisions when final or future regulations are issued, including the following:

- **Coverage of Evidence-Based Items or Services.** We support the regulatory provisions that require coverage for items or services based on the recommendations of the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA).³ Health insurance plans have always looked to the USPSTF and the ACIP for guidance on appropriate clinical preventive services and immunization recommendations, and evidenced-based children's health guidelines. We look forward to providing input to HRSA on the development of the women's health recommendations and encourage HRSA to adopt proven evidence review processes and approaches, such as those used by the USPSTF, in support of this initiative. The regulatory provisions and explanations included in the preamble are a positive step forward for promoting evidence-based care and for increasing consumers' access to clinical preventive services.

² 75 Fed. Reg. 41726, at 41732, 26 C.F.R. §54.9815-2713T(a)(5), 29 C.F.R. §2950.715-2713(a)(5), and 45 C.F.R. §147.130(a)(5).

³ 26 C.F.R. §54.9815-2713T, 29 C.F.R. §2950.715-2713, and 45 C.F.R. §147.130 (specifying coverage for items and services that have a rating of A or B in the current recommendations of the USPSTF; immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the ACIP; for infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the HRSA; and with respect to women, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the HRSA, as long as they are not otherwise addressed by the recommendations of the USPSTF. The complete list of recommendations and coverage guidelines is available at <http://www.HealthCare.gov/center/regulations/prevention.html>.)



- **The “Primary Purpose” of an Office Visit.** Identifying the “primary purpose” of an office visit will be a key component of the proper delivery of a preventive service by primary care health professionals (i.e., whether the primary purpose of an office visit is for a preventive or other health service).⁴ We fully support the agencies’ examples and explanations⁵ for how the regulatory requirements will apply in practical situations, and we believe that these clarifications will help consumers understand when and how preventive services can be obtained without cost-sharing.
- **Out of Network Charges.** In addressing the area of preventive services, we appreciate that the regulatory requirements: (1) support coverage for recommended preventive services delivered by in-network providers; and (2) allow plans or issuers that cover out-of-network preventive services to have flexibility in assessing whether to impose cost-sharing requirements for recommended preventive services.⁶ We believe the regulations are important because they provide ways through which preventive services can be covered with no cost-sharing for consumers through in-network health care providers and emphasize a primary care model that will help ensure continuity of care. At the same time, the regulations do not restrict the ability of consumers to obtain recommended preventive services on an out-of-network basis if their health plan or insurance coverage provides for such options.
- **Medical Management Techniques.** One of the challenges of implementing the clinical preventive service recommendations and guidelines is understanding how they will be used by various primary care health professionals in clinical practice. The preamble and the regulations explain⁷ that plans and issuers can use reasonable medical management techniques to determine coverage limitations 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. Medical management tools help ensure patients receive the right care at the right time and offer individuals assistance in managing their own care and improve personal health outcomes and health status. We support this provision and believe the use of reasonable medical management techniques will help facilitate the appropriate application of the recommendations and guidelines in real-life situations for the benefit of consumers.
- **Regulatory Effective Date and Changes to Recommended Preventive Services.** Consumers, plan administrators, health care professionals, and other stakeholders will

⁴ 26 C.F.R. §54.9815-2713T(a)(2), 29 C.F.R. §2950.715-2713(a)(2), and 45 C.F.R. §147.130(a)(2).

⁵ 75 Fed. Reg. 41728.

⁶ 26 C.F.R. §54.9815-2713T(a)(3), 29 C.F.R. §2950.715-2713(a)(3), and 45 C.F.R. §147.130(a)(3).

⁷ 75 Fed. Reg. 41729, 26 C.F.R. §54.9815-2713T(a)(4), 29 C.F.R. §2950.715-2713(a)(4), and 45 C.F.R. §147.130(a)(4).



need adequate time to understand and implement the new regulatory requirements as well as future changes to required preventive services. We support the approach taken in the IFR to provide flexibility in adopting the coverage requirements, including (1) providing at least a one-year interval between the date a recommendation is issued and the plan or policy year for which coverage is required; (2) making all new recommendations available on the healthcare.gov website; and (3) clarifying that coverage for services is not required (or cost-sharing may be imposed) when an item or service ceases to be recommended. We believe these regulations will enable health benefits and coverage to keep pace with the recommended changes to preventive services based on the scientific evidence without requiring the agencies to issue new rules.

While we support the interim final regulations, we have identified a few areas where we believe technical clarification or guidance is needed to help promote consistency in the understanding and interpretations of the new regulatory requirements. We identify these provisions in Appendix A and offer recommended clarifications for your consideration.

AHIP remains committed to continued collaboration and our members stand ready to provide information in support of the effective implementation of the IFR's provisions regarding coverage of recommended preventive services. We appreciate the opportunity to comment on this important expansion of coverage for evidence-based clinical preventive services.

Sincerely,

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

Carmella Bocchino
Executive Vice President of Clinical Affairs & Strategic Planning

Attachment:



Appendix A ***Technical Clarifications***

1. Coding and Billing Office Visits

Issue: Additional guidance related to appropriate coding and billing practices may be needed.

Discussion: The regulations recognize that a variety of health care services can be provided separately or concurrently with clinical preventive services. We agree that it is appropriate for the regulations to outline how billing practices can affect whether cost-sharing requirements apply in an individual's situation (e.g., whether preventive services are separately billed or submitted in conjunction with other services), and that in some situations it is necessary to look to the "primary purpose" of an office visit to assess whether receiving preventive services was the primary reason that an individual sought health care services.⁸

The regulations highlight the practical importance of primary care health care professionals understanding how to appropriately bill for health care services. Often, appropriate billing is dependent on medical coding and these practices can be complex. Health care professionals will need additional clarification and guidance to understand the regulations and to make process and information systems changes to correctly identify when an office visit is primarily for the purpose of a recommended preventive service. To promote greater understanding of the regulatory requirements for primary care health professionals, the Department of Health and Human Services (HHS) should evaluate existing and emerging coding approaches to assess whether more specific or new codes (e.g., how the use of new or existing modifiers can be used in coding) capture the primary purpose of an office visit, thereby ensuring that individual consumers will be able to appropriately access covered preventive services without incurring any cost-sharing.

Recommendation: HHS should convene a public workshop to solicit feedback on how the current coding and billing practices relate to recommended preventive services.

If needed, a voluntary working group of public and private stakeholders should be established to evaluate existing and emerging coding practices and opportunities to ensure more consistent implementation of the preventive services regulations. If current approaches for identifying the receipt of a recommended preventive service as the "primary purpose" of an office visit could benefit from improvement, the working group should make recommendations on appropriate coding practices.

⁸ 26 C.F.R. §54.9815-2713T(a)(2), 29 C.F.R. §2950.715-2713(a)(2), and 45 C.F.R. §147.130(a)(2).



2. *Translating the Preventive Services Recommendations for Clinicians Into Benefit Designs and Coverage Policies*

Issue: Translating evidence-based preventive services recommendations for clinical practice into sound public and private health benefit designs and coverage policies requires practical application of clinical options and appropriate medical management.

Discussion: In some situations, translating evidence-based preventive service recommendations from clinical practice into public and private health benefit designs can be reasonably straightforward, but in other situations, interpreting and applying the regulatory requirements and the recommendations will present challenges. For example, the ACIP's evidenced-based and age-specific recommendations for routine child, adolescent, and adult immunizations have been successfully incorporated into public and private benefit designs and coverage policies. We expect that future implementation efforts of the ACIP's recommendations related to routine child, adolescent, and adult immunizations will not present significant questions or other operational challenges.

By contrast, the recommendations of the USPSTF^{9,10} were created to provide clinical guidance in primary care around an expansive range of topics in twelve clinical categories. Some of the A and B recommendations will be subject to interpretations which can lead to variations in the recommended preventive services provided to consumers.¹¹ We support the intent of the USPSTF recommendations to provide a primary care professional flexibility when tailoring a preventive service to an individual, allow for appropriate medical management of the recommended preventive service,¹² and encourage shared decision-making between the primary care professional and his or her patient.

⁹ See, The USPSTF information located on the Internet at:

<http://www.guideline.gov/content.aspx?id=15204#Section432> (noting that the USPSTF: (1) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition; (2) develops recommendations that are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service; (3) recognizes that clinical or policy decisions involve more considerations than solely the body of evidence; and (4) encourages clinicians and policy-makers to understand the evidence but individualize decision making to the specific patient or situation.

¹⁰ See, the USPSTF information located on the internet at: <http://www.ahrq.gov/clinic/uspstfix.htm> (noting that "The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services (such as screening, counseling, and preventive medications) and develops recommendations for primary care clinicians and health systems. These recommendations are published in the form of "Recommendation Statements.")

¹¹ E.g., 33 of the 45 USPSTF A and B recommendations are for screening or risk assessment services, but five of the preventive screening recommendations also include references to counseling, behavioral interventions or other interventions, each presenting different implementation challenges to primary care clinicians, group health plans, and insurance issuers.

¹² See 9 above



We have identified five areas that we believe the Agencies should include when final regulations or guidance are issued. In each of these situations, reasonable medical management processes should apply:

- **Counseling and Treatment.** Several of the USPSTF A and B recommendations include counseling as an intervention (e.g., obesity screening for adults, healthy diet for high risk patients, and tobacco use). The language of the USPSTF's recommendations provides flexibility for the primary care professional to work with an individual patient to tailor an effective and agreed-upon service. Reasonable medical management processes should be used to define the scope of the covered clinical service, including the frequency, method, treatment, or setting of the counseling intervention.
- **Primary Care and Counseling Referrals.** USPSTF provides guidance for clinicians in primary care. Some patients who are screened in primary care settings will require follow-up treatment, and often will need to be referred to specialists or other health care providers. In these cases, where patients are referred outside the office practice for further counseling services, we believe that the intent of the IFR is to apply the coverage with no cost-sharing provision to the specific recommended preventive service (screening, counseling, or other intervention) provided by the patient's primary care clinician in the primary care setting, with plans using reasonable medical management approaches to administer this benefit.
- **Recommended Frequency:** When the recommendation or guideline provides a range of frequencies for the recommended preventive service, regulations should clarify that the coverage with no cost-sharing requirement for the preventive service pertains to the minimum frequency stated in the guideline.
- **Over the Counter (OTC) Medications.** The USPSTF A and B recommendations for screening for iron deficiency anemia in pregnant women, folic acid supplementation for women planning or capable of pregnancy, use of aspirin for the reduction of myocardial infarction or ischemic strokes, and tobacco use counseling reference several OTC medications including: (1) iron supplementation; (2) folic acid or multivitamin; (3) aspirin; and (4) nicotine replacement therapy (e.g., gum and lozenge).¹³ We believe the intent of the USPSTF recommendations was for specific

¹³ See, The Food and Drug Administration (FDA) website located on the Internet at: <http://www.fda.gov/aboutfda/centersoffices/cder/ucm093452.htm> (stating that the FDA, as the primary regulator of prescription and OTC drugs recognizes that OTC drugs: (1) play an increasingly vital role in America's health care system; (2) are those drugs that are available to consumers without a prescription; (3) generally have benefits that



individuals to continue to use cost-effective, easily-accessible OTC medications as they currently do, without a prescription or requirement for inclusion in health plan benefit designs. We support the interim final regulations that provide for appropriate medical management processes, including those for OTC medications, reaffirm that clinician counseling recommending use of OTC medications is the recommended preventive service, and that the OTC medications are not included as covered recommended preventive services

- **Pharmacotherapy.** Recommended preventive services such as screening for certain conditions (e.g., screening for blood pressure, type 2 diabetes or cholesterol levels) may lead a health care professional to prescribe medications to treat an individual's illness, disease, or condition. We note that the preamble to the interim final regulations clarifies that treatments generally are not considered part of the recommended preventive services.¹⁴ We believe that pharmacotherapy, when referenced, are treatment interventions and not intended to be included as part of the covered preventive benefit. We support the interim final regulations that provide for appropriate medical management processes for recommended preventive services.

Recommendation: Final or future regulations should: (1) clarify that the regulations apply only to the specific recommended preventive services; (2) explain that related health care services or interventions that are recommended by a health care professional may be beyond the scope of the covered preventive services for an office visit; (3) reinforce that reasonable medical management processes can apply; and (4) advise stakeholders that the USPSTF, ACIP or HRSA recommendations and the schedules or periodicity charts issued by these entities or agencies should be consulted as they contain pertinent information that could affect whether or not a preventive service is recommended for a specific individual.

3. *State Preventive Services Requirements*

Issue: More information or guidance may be needed so that State requirements for recommended preventive services can be administered in addition to the federal preventive services regulatory requirements.

Discussion: States have existing preventive services requirements in a number of areas, particularly related to the screening of newborns¹⁵ or for other public health purposes. The

outweigh their risks and have a low potential for misuse and abuse, (4) can be used by consumers for self-diagnosed conditions; (5) should be adequately labeled by the manufacturer; and (6) do not need health practitioners for the safe and effective use of the product.

¹⁴ 75 Fed. Reg. 41728.

¹⁵ See, <http://genes-r-us.uthscsa.edu/nbsdisorders.pdf>.



preamble explains¹⁶ that State requirements can continue to apply, unless a State standard or requirement prevents the application of the preventive services requirements. As such, we think it would be helpful for the federal agencies and State officials to assess whether any State preventive coverage guidelines conflict with or prevent the application of the federal preventive services requirements.

Recommendation: The federal agencies should work with the National Governor’s Association, National Association of Insurance Commissioners, and other State representatives to assess and provide guidance on whether any State preventive coverage guidelines conflict with or prevent the application of the federal preventive services requirements.

4. *Value Based Benefit Designs*

Issue: The preamble indicates that the agencies will issue future guidance for value-based benefit designs.¹⁷

Discussion: We support the development of future guidance for value-based benefit designs and how providing recommended preventive services increases the quality and value of health care provided to individuals. Our understanding is that this is a new and emerging area with experimentation currently underway, and there are no commonly-held or consistent definitions for what constitutes value-based benefit designs.

Recommendation: AHIP supports flexibility in determining what constitutes a value-based insurance design, but we believe that more clear and consistent information is needed for group health plans and insurers who may want to utilize or expand on such designs in the future.

When developing future guidance, the Departments of Labor, Health and Human Services, and the Treasury should provide a clear definition of what constitutes “value-based insurance designs” that are currently in the marketplace or are emerging, innovative practices.

5. *Excepted Benefits*

Issue: Final or future regulations should clearly define “excepted benefits” as outside the scope of the preventive services requirements.

¹⁶ See generally, 75 Fed. Reg. 41727-33.

¹⁷ 75 Fed. Reg. 41729.



Discussion: We recommend the incorporation of language to clarify the continued exemption for “excepted benefit” products from the new preventive services mandate. Congress recognized the distinction between comprehensive medical coverage and “excepted benefits” when it excluded these benefits from the application of the insurance market provisions established under the Health Insurance Portability and Accountability Act (HIPAA). The inapplicability of the Affordable Care Act’s insurance and market reform provisions to excepted benefits has been previously acknowledged for the new Internet portal and in the preamble of the Interim Final Rules for Grandfathered Health Plans, and we ask that the same recognition also be made with respect to this IFR.

Recommendation: The federal agencies should clarify the scope of the IFR with an acknowledgement of its application to comprehensive, major medical coverage only, and not to the benefits classified as “excepted benefits” under subsection 2791(c) of the Public Health Service Act.

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