

September 30, 2011

***BY ELECTRONIC DELIVERY***

Donald Berwick, M.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act; Interim Final Rules [CMS-9992-IFC2]**

Dear Administrator Berwick:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) interim final rules regarding coverage of preventive health services by group health plans and health insurance issuers in the group and individual markets under provisions of the Affordable Care Act (ACA).<sup>1</sup> BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new preventive tools and treatments and ensuring patient access to them. BIO membership includes both current and future vaccine developers and manufacturers who have worked closely with the public health and advocacy communities to support policies that help ensure access to innovative and life-saving vaccines for all individuals. Therefore, we continue to monitor those policies and rules that could both positively and negatively impact access to vaccinations and subsequently, immunization rates.

With the goal of ensuring patient access to immunizations, BIO recommends two modifications to the interim final rules. First, it is important that group health plans and health insurance issuers be required to provide first dollar coverage for the full set of vaccines recommended for children, adolescents, and adults by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), regardless of the nature of the recommendation, as published in the CDC's annual immunization schedules. Second, the interim final rules should include clear language defining "in-network providers" for

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<sup>1</sup> 76 Fed. Reg. 46621 (August 3, 2011).



immunizations, allowing for the delivery of immunization services outside physician office settings under the same first dollar coverage provisions that apply to physician offices.

## **I. Covered Immunizations**

BIO feels strongly that all immunizations published annually in the CDC's immunization schedules should qualify for first dollar coverage under the ACA. This includes the "Recommended Immunization Schedule for Persons Aged 0 Through 6 Years," the "Recommended Immunization Schedule for Persons Aged 7 Through 18 Years," the "Catch-up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Who Are More Than 1 Month Behind," and the "Recommended Adult Immunization Schedule" and footnotes.<sup>2</sup> These vaccines have been reviewed and their appropriate use recommended by the ACIP and adopted by the CDC. Vaccines in these schedules are recommended (along with dosing information) for *routine use* (all members of a defined age group), *permissive use* (if a provider deems it appropriate and a patient wishes protection), *catch-up immunization* (for missed series/doses), and *at-risk use* (for defined high-risk groups).

For vaccines that are recommended for permissive use, the decision about whether to immunize is left to the patient and their health care provider, allowing for consideration of a patient's individual risk factors and health conditions. Vaccines recommended by a provider in scenarios such as this should also be covered at first dollar by group health plans and health insurance issuers. According to the ACA, "a group health plan and a health insurance issuer offering group or individual health insurance coverage shall at a minimum provide coverage for and shall not impose any cost-sharing requirements for immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved."<sup>3</sup> In accordance with the law, BIO recommends that the interim final rules be modified to help ensure patients have access to all ACIP-recommended vaccines deemed appropriate by a health care provider for the individual.

## **II. In-Network Providers**

BIO recommends that the interim final rules include clear language allowing for the delivery of immunization services in alternative settings, as appropriate, under the same first dollar coverage provisions as applicable in physician offices. Many state laws allow for the provision of immunization services in complimentary, non-physician office settings, such as retail pharmacies and school-based clinics, to have an expansive network of locations and providers. Alternative settings increase access to immunizations, especially for the adult population. For example, more than 150,000 pharmacists are currently trained to administer vaccines in the

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<sup>2</sup> Centers for Disease Control and Prevention. Immunization Schedules. Available at: <http://www.cdc.gov/vaccines/recs/schedules/default.htm>.

<sup>3</sup> P.L. 111-148 Title I(A) § 1001(A)(2713)(a)(2).

U.S.,<sup>4</sup> and according to data from the CDC, during the 2010-2011 season, nearly 20% of adult vaccines were administered in retail pharmacies.<sup>5</sup>

We suggest that the interim final rules be modified to clarify that a network of providers for immunization services may include those health care providers and locations allowed by state law to provide such services. Furthermore, BIO recommends that the rules make clear that these services should be administered without cost-sharing.

### **III. Conclusion**

While BIO recognizes the importance of all preventive services, we feel that immunizations are a proven, simple set of interventions that have been shown to have a significant impact on the health of all individuals. Thus, it is important to increase access to immunizations by requiring first dollar coverage of all vaccines recommended by ACIP, and by clarifying that a network of providers for immunization services includes alternative access settings, such as pharmacies.

BIO appreciates the opportunity to comment on the interim final rules for group health plans and health insurance issuers relating to the coverage of preventive services under the ACA. We look forward to continuing to work with CMS and the Department of Health and Human Services to address critical issues related to the provision of preventive services and the implementation of the ACA. Please do not hesitate to contact me for further information or clarification of our comments. Thank you for your attention to this very important matter.

With Sincerest Regards,



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<sup>4</sup> Rothholz M. Role of Pharmacists in Adult Vaccination: Overview from the American Pharmacists Association. Presentation to the National Vaccine Advisory Committee. September 14, 2011.

<sup>5</sup> Centers for Disease Control and Prevention. Place of influenza vaccination among adults – United States, 2010-11 influenza season. *MMWR Morb Mortal Wkly Rep.* 2011;60(23):781-785.