BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 17, 2010

Mr. Jim Mayhew
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 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

Please Refer to OCIIO-9992-IFC

Dear Mr. Mayhew:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Department of Health and Human Services' interim rules for group health plans related to coverage of preventive services under the Patient Protection and Affordable Care Act (ACA).[1] 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.

The inclusion of required first dollar coverage for immunizations recommended by the Centers for Disease Control and Prevention (CDC) will help millions more Americans access these life-saving products. While many private health insurers currently offer immunization coverage for children and adolescents, not all offer these

[1] 75 Fed. Reg. 41726-60 (July 19, 2010).

services at first dollar or cover all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for the adult population. Full implementation of this provision of the Act could have a very positive effect on the affordability and access to immunizations across all ages. However, we have three major concerns about the interim final rules as currently written.

"In effect" delays a concern

First, the interim rules, as described in the statute, appear to allow health plans to delay such coverage until plan / policy years beginning one year after the "in effect" date of the recommendation. We are concerned that the existing language in the interim final rules may actually significantly delay first dollar insurance coverage of new or recently altered ACIP-recommended vaccines, potentially hampering the effectiveness of these key preventive tools by slowing uptake in the private sector.

Currently, according to data from a publication by America's Health Insurance Plans (AHIP) entitled *2008 Adult Immunization Survey: Practices and Policies of Private Health Insurance Plans,* over 95% of private plans make a coverage decision about a new or recently altered recommended vaccine within 3 months of the ACIP recommendation. Almost 60% of surveyed plans made these changes within one month. Given this evidence that rapid implementation of insurance coverage of newly recommended vaccines is already a standard without official regulations, we believe it would be a step backwards to institute a longer compliance timeline in the regulations.

Allowing for a one year adoption period could lead to an unintentionally negative consequence where newly recommended vaccines or populations are covered in public programs such as Medicaid and Vaccines for Children (VFC) many months, or possibly years, before some private plans offer the same coverage. By statute, the CDC must offer newly recommended vaccines through the VFC program to Medicaid beneficiaries within 90 days of publication in the *Morbidity and Mortality Weekly Report* (MMWR).

In our view coordinating the timing for adoption of new recommendations between the public and private sectors would help ensure that all eligible individuals can benefit from these critical preventive health interventions. Changes to this portion of the rules would also help providers in their implementation of new recommendations as well. Therefore, in keeping with current standard practice among the vast majority of private insurers, BIO encourages HHS to adopt a shorter timeline within which health plans must implement coverage for the recommended immunizations.

Confusion over "trigger" dates

Second, we are also concerned that using three different milestones as "in effect" trigger dates may be confusing to private health plans. According to the examples on Healthcare.gov, the one year start date could be based on: 1) publication of a

recommendation in the MMWR; 2) publication of the annual immunization schedules (usually in early January); or 3) publication of a provisional recommendation (generally within one month of an actual ACIP Committee vote).

BIO recommends that the "in effect" date for any new ACIP recommendation be either the publication of the provisional recommendations or the publication of the official CDC immunization schedules, whichever happens first. There can be anywhere from 3 months (meningococcal vaccine) to 12 months (Herpes Zoster vaccine) between the ACIP vote and actual publication of recommendations in the MMWR. Thus use of publication in the MMWR coupled with the one year allotted adoption time for health plans could mean approximately two years before a new recommendation is fully implemented with required first dollar coverage.

While we recognize the importance of all preventive services, we feel that immunizations are a proven, simple set of interventions that have been shown to have significant impact on the health care all individuals. Vaccines are a relatively low-cost part of the health care system. In a 2009 report to the National Vaccine Advisory Committee (NVAC), an HHS policy analyst reported that the percentage of annual vaccine coverage for all ACIP-recommended vaccines for a family was only 0.8% of the 2009 premiums charged within a large health plan. The historically high impact of immunizations coupled with their relatively low cost and low impact on health insurance premiums should allow health insurers to add them more rapidly to their existing plans, as most in fact already do now.

Alternative access settings

Finally, BIO recommends that the interim final rules include clear language allowing for the delivery of immunization services outside physician office settings under the same first dollar coverage provisions as applicable in physician offices. Many state laws allow for the provision of immunization services in complementary, non-physician office settings, such as retail pharmacies and school-based clinics, to have an expansive network of locations and providers. For example, according to a 2010 study by the RAND Corporation, approximately 17% of seasonal influenza vaccine was administered in retail pharmacies in the 2009-10 season.

We suggest that the language on page 11 of 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, we would recommend that the rules make clear that these services can therefore be administered without cost-sharing.

BIO members strongly support provisions that will help ensure access to proven preventive services, such as vaccinations. We look forward to future opportunities to work with the Department to maximize adoption of the preventive services and quality provisions of the Patient Protection and Affordable Care Act.

Conclusion

BIO appreciates the opportunity to comment on the 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. We look forward to continuing to work with HHS to address these critical issues in the future. Please feel free to contact me at 202-962-6664 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

With Sincerest Regards,

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