

July 5, 2011

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

Re: Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers (CMS-3213-P)

Dear Dr. Berwick:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the proposed rule establishing an influenza vaccination standard for certain Medicare and Medicaid providers and suppliers. 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 membership includes both current and future vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovative and life-saving vaccines for all individuals. BIO fully supports the creation of an influenza vaccination standard for participating providers and suppliers, and we commend the Centers for Medicare and Medicaid Services (CMS) for taking a major step towards increasing influenza vaccination rates among patients. Immunizations have long been considered a proven and cost-effective healthcare intervention for persons of all ages. Vaccine manufacturers are committed to supplying the market and meeting public health needs in the U.S. Over the past years, they have made significant investments in domestic vaccine production capacity and innovations in influenza vaccine administration technologies, and the supply has exceeded demand. Moving forward, manufacturers will maintain their commitment to public health and continue to invest in new capital.

Comments

Our comments focus on the value of a CMS vaccination standard for influenza and the need to also establish vaccination standards for pneumonia and pertussis. We also recommend an additional information collection requirement and address cultural competence with regard to vaccine education.

I. Expansion of Vaccination Standard

BIO agrees with CMS that the proposed influenza vaccination standard will help increase vaccination coverage among patients, thereby reducing influenza morbidity and mortality. Influenza has a significant public health impact in the United States each year, causing, on average, approximately 226,000 hospitalizations and 36,000 deaths.¹ Vaccination is the primary method for preventing influenza infection and has been proven to be safe and effective.² Despite the benefits, historically, influenza vaccination rates have been low, reaching a record 42.8% coverage rate among persons aged ≥ 6 months during the 2010 – 2011 season.³ Opportunities exist to improve vaccination rates, especially among adults.

While people cite a variety of reasons for not receiving influenza vaccination, many often report that their healthcare provider did not recommend or offer the vaccine.⁴ During the 2010 – 2011 season, medical settings were the most common place for influenza vaccination.⁵ Yet, the vaccine is not offered to patients in many medical settings,⁶ representing a missed opportunity for vaccination. By requiring certain providers and suppliers, such as hospitals and federally qualified health centers (FQHCs), to offer influenza vaccine to patients as a Condition of Participation (CoP) or a Condition for Certification (CfC), vaccination coverage will most likely increase, as it did in long-term care facilities after CMS introduced an influenza vaccination standard in that setting in 2005.⁷ BIO believes that the cornerstone of any vaccine-related quality measure is the offer of vaccine, and we applaud CMS for recognizing this in the proposed rule.

Just as there are missed opportunities for vaccinating patients against influenza, there are many missed opportunities to vaccinate patients against pneumonia and pertussis. These vaccines have been traditionally offered in hospitals. However, vaccination coverage in this setting remains perilously low.

Like influenza, pneumonia and pertussis have an adverse impact on public health. The Centers for Disease Control and Prevention (CDC) estimates that in 2007, 1.2 million people in the U.S. were hospitalized with pneumonia and more than 52,000 died from the disease. There is a large body of evidence supporting the concept of simultaneous vaccination with influenza and pneumococcal vaccines. Following the introduction of

¹ CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Morb Mortal Wkly Rep.* 2010;59(RR-08):1-62.

² HHS. Action Plan to Prevent Healthcare-Associated Infections: Influenza Vaccination of Healthcare Personnel. 2010. http://www.hhs.gov/ash/initiatives/hai/tier2_flu.html.

³ CDC. Interim results: state-specific influenza coverage – United States, August 2010 – February 2011. *MMWR Morb Mortal Wkly Rep.* 2011;60(22):737-743.

⁴ Johnson D, Nichol K, Lipczynski K. Barriers to adult immunization. *Am J Medicine.* 2008;121:s28-S35.

⁵ CDC. Place of influenza vaccination among adults – United States, 2010-11 influenza season. *MMWR Morb Mortal Wkly Rep.* 2011;60(23):781-785.

⁶ Infectious Diseases Society of America. Actions to strengthen adult and adolescent immunization coverage in the United States: policy principles of the Infectious Diseases Society of America. *Clin Infect Dis.* 2007;44:e104-e108.

⁷ 76 FR 25461 (2011-05-04).

comprehensive performance measures in the Veterans Health Administration (VA), influenza and pneumonia vaccination rates rose to 77% and 80% respectively among the adult population, and pneumonia hospitalization rates decreased by 50%.⁸ As a result, the adult patient population was healthier and the VA saved approximately \$117 for each vaccine administered.⁹

Pertussis, commonly called whooping cough, is a highly contagious upper respiratory disease. In 2010, 9,477 cases of pertussis (including ten infant deaths) were reported throughout California, representing the highest number of cases reported in 65 years and the highest incidence in 52 years.¹⁰ Pertussis vaccination is recommended by the Advisory Committee on Immunization Practices (ACIP) for adolescents and adults, and it protects the individual as well as those around them, including infants under the age of 6 months who are most severely impacted by the disease. While some hospitals have implemented standing orders for pertussis vaccination in postpartum women, individual institutional policies may not adequately increase vaccination rates on a larger scale. To improve pertussis vaccination coverage, a broader federal policy is needed, such as the influenza vaccination standard proposed by CMS for participating providers and suppliers.

Recommendation: BIO recommends that CMS include pneumonia vaccination and pertussis vaccination in its standard.

II. Additional Information Collection Requirement

To further increase vaccination rates in the future, BIO believes that it is important to include an additional information collection requirement in the final rule. Under the proposed rule, providers and suppliers are required to document whether a patient refuses influenza vaccination. However, they are not required to document the reason for refusal. BIO believes the addition of this information collection requirement would allow CMS, CDC, and other public health entities to better assess the reasons for low vaccination coverage among the patient population.

To minimize the additional time and cost associated with this requirement, CMS could conduct a literature search to identify common reasons for refusal and then develop a set of standardized reasons from which patients could choose. The collection of this data would allow CMS, CDC, providers, and suppliers to tailor patient educational materials and immunization initiatives to more accurately address barriers to vaccination.

Recommendation: BIO recommends that CMS require providers and suppliers to document the reason for the patient's refusal of vaccination.

⁸ Jha A, Wright S, Perlin J. Performance measures, vaccinations, and pneumonia rates among high-risk patients in Veterans Administration health care. *Am J Public Health*. 2007;97(12):2167-2172.

⁹ Ibid.

¹⁰ CDC. Pertussis (Whooping Cough) – Recent Outbreak Activity. 2011. Available at: <http://www.cdc.gov/pertussis/outbreaks.html>.

III. Cultural Competence & Vaccine Education

CMS requested comments regarding ways to address disparities in vaccination coverage in the final rule. BIO suggests that participating providers and suppliers apply various cultural competency techniques to ensure patients fully understand the risks of vaccine-preventable diseases and the benefits of vaccination. Educational materials should be offered in several languages that are common in the region where the provider or supplier is located, and should include information on the different presentations of influenza vaccines available. It is important that patients be made aware of and offered the various influenza vaccine presentations appropriate for them, based on age and other demographic information.


In the proposed rule, CMS discussed the use of family members and friends as liaisons and third party advocates who could help patients understand vaccination information and communicate with facility staff. Lack of knowledge about the risks of vaccine-preventable diseases and the benefits of vaccination is a barrier to vaccination. BIO believes the use of third party advocates should help overcome this barrier, thereby reducing disparities in vaccination coverage.

Conclusion

As stated by CMS in the proposed rule, CoPs and CfCs are “intended to protect public health and safety and to ensure that high quality care is provided to all persons.” The establishment of a vaccination standard for participating providers and suppliers will help fulfill this mission by reducing the burden of vaccine-preventable diseases. CMS should consider expanding the standard to include pertussis and pneumonia vaccination in addition to influenza vaccination. CMS should also consider requiring providers and suppliers to document the reason vaccination was refused by the patient. The adoption of these recommendations could further improve public health in the U.S.

BIO appreciates the opportunity to comment on the establishment of an influenza vaccination standard for certain Medicare and Medicaid providers. We look forward to continuing to work with CMS to address these critical issues in the future. Please do not hesitate to contact us 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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