

May 7, 2012

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 [CMS-0044-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule specifying the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments.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 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 vaccines for all individuals. We support the use of appropriate, evidence-based objectives and quality measures throughout the healthcare system and we feel that immunizations have long been considered a proven and cost-effective healthcare intervention for persons of all ages.

Comments

BIO supports CMS' Medicare and Medicaid EHR Incentive Programs, which promote the adoption and meaningful use of certified EHR technology. The meaningful use of EHR technology by healthcare providers and hospitals can have a positive impact on immunization rates in the United States by helping eliminate missed opportunities for vaccination as well as avoid over-immunization. In turn, higher immunization rates lead to better health outcomes and cost savings for the healthcare system. Our comments

¹ 77 Fed. Reg. 13698 (March 7, 2012).

focus on CMS' proposals regarding: (1) the core public health objectives for Stage 2; (2) clinical decision support interventions; and (3) clinical quality measures. BIO also comments on the definition of EP. Specifically, BIO supports and recommends the following:

- BIO supports CMS' proposal to make ongoing reporting to immunization registries a core public health objective for Stage 2.
- BIO recommends that at least one immunization clinical quality measure be included in the core set in Table 6 for EPs and that two additional measures be included in Table 8.
- BIO supports the inclusion of new immunization clinical quality measures in the menu set for eligible hospitals and CAHs.
- BIO supports the implementation of clinical decision support interventions that have a strong evidence base, such as clinical decision support interventions linked to immunization measures.
- BIO recommends that CMS request an expansion of the EP definition.

I. Stage 2 Public Health Objectives

Immunization registries, also known as immunization information systems (IIS), help ensure that children, adolescents, and adults receive timely and appropriate immunizations. By age two, over 20% of children in the U.S. have seen more than one immunization provider, making it difficult to track vaccination status.² Similarly, adults often see a number of immunization providers in a variety of settings. As a result, providers often fail to recognize that a patient is due or overdue for vaccinations. Registries help alleviate this problem by securely exchanging a patient's immunization information (e.g. vaccination status, consolidated records) to authorized healthcare providers, allowing them to make informed decisions about which recommended vaccines to administer to a particular patient during an office visit or hospital stay based on the patient's records. Studies show that the use of registries increases immunization rates in children and adults. In a 2004 study, the implementation of a regional immunization registry resulted in a 50% increase in the number of children aged 2 years who were up-to-date on their immunizations.³

Missed appointments and a lack of awareness of immunization schedules are also common reasons for inadequate vaccination.⁴ Registries also help address this problem by facilitating the use of patient reminder/recall systems, which notify patients and parents of upcoming appointments to receive vaccinations (reminders) and contact those

² Every Child by Two. <http://www.ecbt.org/registries/>.

³ Kempe A, Beaty BL, Steiner JF, et al. The regional immunization registry as a public health tool for improving clinical practice and guiding immunization delivery policy. *Am J Public Health*. 2004;94(6):967-972.

⁴ Alemi F, Alemagno SA, Goldhagen J, et al. Computer reminders improve on-time immunization rates. *Med Care*. 1996;34(10 Suppl): OS45-51.

who have missed appointments, urging them to reschedule (recalls). Patient reminder/recall systems have been shown to increase immunization rates in children and adults by 5-20%.⁵ Furthermore, alerting patients and parents of immunizations that are due has proven to be extremely cost-effective in public clinics,^{6,7} private practice offices, and health maintenance organizations.^{8,9}

CMS proposes to make reporting to immunization registries a "core" and required public health objective for Stage 2. In contrast, this was an optional "menu" objective choice for Stage 1. BIO strongly supports the proposed change, which represents a strengthening of this important public health objective. To facilitate the broad and therefore effective use of registries, a large number of providers must have the capability to submit electronic data to these systems. As stated by CMS, the inclusion of this capability in the core set encourages all eligible providers to submit electronic immunization data, regardless of whether it is required by either law or practice.

CMS also proposes that unlike in Stage 1, a failed or one-time submission to immunization registries would not meet the objective for Stage 2. Unless eligible providers meet exclusion criteria, they must successfully submit electronic immunization data from certified EHR technology to registries in an ongoing and routine manner. This proposal also represents a strengthening of the objective, and BIO fully supports it. These proposals are likely to increase the meaningful use of immunization registries, which, as studies show, will positively impact immunization rates in the U.S. for children, adolescents, and adults.

II. Clinical Quality Measures

BIO supports the development and use of appropriate, evidence-based quality measures throughout the healthcare system. Immunization quality measures help ensure that healthcare providers routinely discuss and offer vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system. Performance measures are currently in place for all vaccines in the pediatric and adolescent series with a demonstrated impact on utilization. The health and economic benefits of adult immunization measures became evident following the introduction of performance measures for influenza and pneumococcal vaccinations in the Veterans

⁵ Szilagyi PG, Bordley C, Vann JC, et al. Effect of patient reminder/recall interventions on immunization rates: A review. *JAMA*. 2000;284(14): 1820-1827.

⁶ Linkins RW, Dini EF, Watson G, Patriarca P. A randomized trial of the effectiveness of computer-generated telephone messages in increasing immunization visits among preschool children. *Arch Pediatr Adolesc Med*. 1994;148:908-914.

⁷ Dini EF, Linkins RW, Chaney M. Effectiveness of computer-generated telephone messages in increasing clinic visits. *Arch Pediatr Adolesc Med*. 1995;149:902-905.

⁸ Lieu T, Black S, Ray P, et al. Computer-generated recall letters for underimmunized children: how cost effective? *Pediatr Infect Dis J*. 1997;16:28-33.

⁹ Lieu TA, Capra AM, Makol J, Black SB, Shinefield HR. Effectiveness and cost-effectiveness of letters, automated telephone messages, or both for underimmunized children in a health maintenance organization. *Pediatrics*. 1998;101(4).

Health Administration (VHA) in 1995. Among eligible adults, influenza vaccination rates increased from 27% to 70%, and pneumococcal vaccination rates rose from 28% to 85%, with limited variability in performance between networks; pneumonia hospitalization rates decreased by 50%, and it is estimated that the VHA saved \$117 for each vaccine administered.¹⁰

CMS proposes to change the approach to clinical quality measure (CQM) reporting, requiring EPs to report 12 CQMs and eligible hospitals and CAHs to report 24 CQMs in total. CMS seeks feedback on a list of 125 potential measures for EPs and 49 potential measures for eligible hospitals and CAHs as well as comments on the proposed reporting options for EPs. CMS proposes the following 2 options for EPs:

- Option 1a: EPs would report 12 CQMs from those listed in Table 8, including at least 1 measure from each of the 6 domains.
- Option 1b: EPs would report 11 “core” CQMs listed in Table 6 plus 1 “menu” CQM from Table 8.

While Table 8 includes a number of immunization CQMs on which EPs could potentially report in compliance with Option 1a, Table 6 does *not* include any immunization CQMs in the core set. Thus, under Option 1b, it is unlikely that EPs will report immunization measures as part of the EHR Incentive Program. Considering immunization measures’ impact on uptake and fulfillment of several domains including “Population / Public Health” and “Clinical Process / Effectiveness,” BIO recommends that at least one of the following immunization CQMs listed in Table 8 be included in the core set in Table 6 if CMS chooses Option 1b, or that all the measures below be considered for addition to the measure set if CMS chooses Option 1a, in order to enable providers serving individuals of all ages to potentially report on immunization measures.

- NQF 0038 – Childhood Immunization Status
- NQF 1407 – Immunization for Adolescents
- NQF 0041 – Preventive Care and Screening: Influenza Immunization
- NQF 0043 – Pneumonia Vaccination Status for Older Adults
- NQF 0617 – High Risk for Pneumococcal Disease – Pneumococcal Vaccination
- NQF 0399 – Hepatitis C: Hepatitis A Vaccination in Patients with HCV
- NQF 0400 – Hepatitis C: Hepatitis B Vaccination in Patients with HCV

CMS proposes that eligible hospitals and CAHs report 24 CQMs from a menu of 49 CQMs listed in Table 9, including at least 1 CQM from each of the 6 domains. The following two immunization CQMs are listed in Table 9:

¹⁰ 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.

- NQF 1653 – IMM-1 Pneumococcal Immunization (PPV23)
- NQF 1659 – IMM-2 Influenza Immunization

BIO strongly supports the inclusion of these new measures in the menu set for eligible hospitals and CAHs. These measures are of particular importance in hospitals, where immunizations can be readily administered to prevent the transmission of pneumococcal disease and influenza, which are relatively common and have an adverse impact on public health and patient safety. Nosocomial influenza outbreaks, and associated secondary pneumococcal infections, in hospitals result in longer stays and greater morbidity and mortality among patients.¹¹ Vaccination is the primary method for preventing both these infections and can also prevent the need for antibiotic treatments and the subsequent spread of antibiotic resistance. BIO also recommends that CMS adopt a broader pneumococcal immunization measure to allow for inclusion of new adult vaccines in this therapeutic area. The proposed measure, NQF 1653, is tied too specifically to pneumococcal polysaccharide vaccine (PPV23) and may not allow for the advent of new vaccines against these important diseases.

III. Clinical Decision Support Interventions

In Stage 2, CMS proposes requiring EPs and hospitals to adopt 5 clinical decision support (CDS) interventions related to 5 or more CQMs on which they are expected to report. The CDS interventions are expected to improve performance on these CQMs; however, providers are not required to show an actual improvement in performance. Rather, providers must use the goal of improvement in performance for a CQM when selecting a CDS intervention to implement.

In its discussion of this proposal, CMS uses a CQM on influenza immunization in patients 50 years and older (NQF 0041, PQRI 110) as an example of a CDS intervention.¹² The CDS tool would trigger an alert in the EHR system that prompts the EP to check the influenza immunization status of a patient age 50 or older during the office visit. The EP could then counsel the patient about the importance of influenza vaccination, offer influenza vaccination, or refer the patient to another provider for influenza vaccination.

BIO supports the implementation of CDS interventions that have a strong evidence base. Thus, we find the aforementioned example of a CDS intervention related to immunization to be particularly suitable. CDS interventions linked to immunization measures may significantly improve clinical performance and patient health. Most adults (79% to 85%, depending on the vaccine) are likely to receive a vaccination if their healthcare provider recommends it.¹³ Similarly, adults commonly cite the absence of a

¹¹ Lindley M, Yonek J, Ahmed F, Perz J, Torres G. Measurement of influenza vaccination coverage among healthcare personnel in US hospitals. *Infect Control Hosp Epidemiol.* 2009;30:1150-1157.

¹² 77 Fed. Reg. 13698 (March 7, 2012). See pg. 13715.

¹³ Johnson D, Nichol K, Lipczynski K. Barriers to adult immunization. *Am J Med.* 2008;121:S28-35.

doctor's recommendation as the reason for not receiving a vaccine.¹⁴ The CDS tool can be used to notify providers to offer recommended immunizations to patients, making the administration of vaccines a routine part of all healthcare encounters and helping increase immunization rates.

IV. Eligible Professionals

While CMS' Stage 2 proposals for the EHR Incentive Program are likely to expand the meaningful use of EHR technology by immunization providers who are EPs, they may not influence the use of EHRs by providers who fall outside the definition of EPs. In the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, the term "eligible professionals" is narrowly defined. Medicare EPs include only physicians, dentists, podiatrists, optometrists, and chiropractors. Medicaid EPs include physicians, nurse practitioners, nurse midwives, dentists, and some physician assistants. In addition, Medicaid EPs must meet certain criteria with regard to Medicaid patient volume and practice setting. Key immunization providers, such as pharmacists and healthcare providers practicing at local health departments, are not designated as EPs.

Vaccines can be delivered in a wide variety of settings. Many state laws allow for the provision of immunization services in complimentary, non-physician office settings, such a retail pharmacies and school-based clinics, which increases access to immunizations, especially for the adolescent and adult population. For example, more than 150,000 pharmacists are currently trained to administer vaccines in the U.S.,¹⁵ and according to data from the CDC, during the 2010-2011 season, nearly 20% of adult influenza vaccines were administered in retail pharmacies.¹⁶ Local health departments also commonly serve as vaccination sites. During the 2010-2011 season, 4.4% of adults received their influenza vaccine at a local health department.¹⁷

To successfully achieve the goals laid out in the National Quality Strategy and to implement the widespread exchange of immunization information and data throughout the U.S. healthcare system, BIO recommends that CMS request an expansion of the EP definition. This expansion would further increase the adoption and meaningful use of EHRs, thereby improving health outcomes and healthcare quality.

Conclusion

¹⁴ Ibid.

¹⁵ Rothholz M. Role of Pharmacists in Adult Vaccination: Overview from the American Pharmacists Association. Presentation to the National Vaccine Advisory Committee. September 14, 2011.

¹⁶ 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.

¹⁷ Ibid.

While BIO recognizes the importance of all preventive services, immunizations are a proven, simple set of interventions that have been shown to have a significant impact on the health of all individuals. Thus, BIO supports the use of certified EHR technology by providers to utilize immunization registries, report immunization CQMs, and implement CDS interventions, all of which will help increase immunization rates and thereby improve public and population health.

BIO appreciates the opportunity to comment on the proposed rule specifying Stage 2 criteria for the Medicare and Medicaid EHR Incentive Programs. We look forward to continuing to work with CMS to address these critical issues in the future. Please contact me 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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