June 3, 2016

BY ELECTRONIC DELIVERY

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
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Washington, D.C. 20201

Re: Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information (RFI) Regarding Assessing Interoperability for MACRA

Dear Dr. DeSalvo:

The Biotechnology Innovation Organization (BIO) is pleased to submit the following comments in response to the *Request for Information (RFI) Regarding Assessing Interoperability for MACRA* (the "RFI").[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO supports the goal expressed in the Medicare Access and CHIP Reauthorization Act of 2015 with regard to achieving widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide. This goal is an important component of a broader public health aim to ensure that providers have access to the information they need to work with patients to make timely and appropriate clinical decisions. In particular, we agree with the Office of the National Coordinator for Health Information Technology's (ONC's) approach to developing and implementing metrics to assess whether the MACRA goal has been set. However, to facilitate the uptake and use of EHR technology to the benefit of patients' care, we urge ONC to broaden the definitions of interoperability and population to which the metrics apply.

First, MACRA defines interoperability as the ability of two or more health information systems or components to: (1) Exchange clinical and other information and (2) use the information to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improve patient outcomes. In implementing this definition, BIO urges ONC to consider whether and how these data are able to be utilized, in

[1] 81 Fed. Reg. 20,651 (April 8, 2016).

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a de-identified manner, for research purposes, insofar as the research's ultimate aim is to contribute to improvements in patient care. For example, de-identified genomic and phenotypic data collected from EHRs can increase the statistical power—and, in turn, the reliability, translatability, and utility—of big data analyses that seek to better characterize the natural history of diseases and/or improve the appropriate use of healthcare interventions based on real-world evidence. Additionally, with the appropriate controls in place (e.g., to protect patient privacy), EHR data can help to connect clinical trial researchers with interested patients through trusted third-party mechanisms. This could be beneficial to both stakeholders, as it can often be difficult for patients to find information about relevant clinical trials, and similarly, challenges in clinical trial recruitment—especially for conditions affecting only a small number of people—can delay the overall drug development process. Thus, broadly including the use of EHR data in research as an aspect of the metrics ONC is developing can facilitate and encourage this use to the benefit of patient care.

Second, BIO urges ONC to define the population establishing and utilizing interoperable EHR to include immunization registries and community immunizers that are often the providers of choice for many individuals. Specifically, BIO urges ONC to include measures for interoperability to better understand gaps in adult immunization rates in the Medicare population. This can be accomplished by piloting the integration of Medicare claims data, data from State All-Payer Claims Databases (APCDs), data from state immunization information systems (i.e., immunization registries), and data extracted from EHRs. As a complementary effort, ONC should work with relevant federal agencies—Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and other Department of Health and Human Services (HHS) agencies—to augment the ONC Interoperability Roadmap.

Meaningful use measures that are specific to immunizations, and the connectivity between and among immunization registries, already exist. Thus, BIO recommends that ONC draw from these measures in developing the metrics specified by the RFI. Specifically, the ONC should utilize immunization-specific metrics that ensure that interoperability requirements under MACRA take into account:

- Structured immunization history data (including National Drug Codes (NDCs) for vaccines that are best suited to support immunization inventory management);
- The degree of integration between immunization registries, supplied by EHR data; and
- A comprehensive measures data set (including: date of administration; vaccine manufacturers; vaccine lot number; name and title of administrator of vaccine; address of facility where permanent record resides; vaccine information statement; and date of the vaccine information statement and the date on which it is given to the patient.

Ensuring that the flow of this information is incorporated as a metric of sufficient EHR integration will promote providers' access to the most complete and up-to-date information on a patient's immunization history to inform discussions about what vaccines a patient may need based on nationally recommended immunization recommendations.

BIO appreciates ONC's attention to these comments, and reiterates our recommendation that ONC operationalize the definitions of "interoperability" and

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"population" in as inclusive a manner as is practically possible. We appreciate your attention to this important matter, and encourage the Agency to reach out with any questions.

Sincerely,

/s/

Laurel Todd
Vice President, Healthcare Policy and Research

/s/

Phyllis Arthur
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