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December 20, 2018

Robert R. Redfield, MD  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329-4027

**RE:** RFI 75D301-19-Q-69537

**SUBMITTED BY:**

Electronic Health Record Association (Trade Association)  
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Sarah Willis-Garcia, Program Manager  
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Dear Dr. Redfield,

Thank you for the opportunity to respond to the Request for Information regarding the National Test Collaborative (75D301-19-Q-69537). On behalf of the 35 member companies in the Electronic Health Record Association (EHRA), it is our pleasure to share our insights and expertise with the Centers for Disease Control and Prevention.

Established in 2004, EHR Association brings together companies that develop, market, and support electronic health records (EHRs) to collaborate on issues that impact our businesses and our collective customers — hospitals and providers that represent the majority of EHR users in the U.S. We work together to speak with a unified voice on these topics in a non-competitive, collegial effort to understand, educate, and collaborate with all stakeholders engaged with EHRs and health information and technology (IT).

The EHR Association appreciates the focus on real-world testing, as identified in the 21st Century Cures Act. As we have stated in prior feedback, on the roll-out of interoperability capabilities under Meaningful Use and Certification Editions, wide

deployment should be preceded by initial (pilot) deployments to validate the appropriateness and maturity of the proposed standards, implementation guides, and approach. In many ways, pilots as described above would have the ability to provide real-world test opportunities beyond the limitations of connectathons, sandboxes, and test harnesses (recognizing the substantial value they do provide and are essential in the development and deployment of interoperability).

We assume CDC's proposal to do "real-world testing" is defined as using actual, operational environments with real data to validate that standards, infrastructure, and processes achieve the desired outcome. We note that in many cases, EHR developers already move our solutions through a pilot/beta test/early deployment phase before making it generally available for deployment. However, we recognize the scope of these phases are typically more focused on immediate capabilities and data connections for a singular organization, and less so on wider consistency considerations across developers and organizations.

While we do not believe that the real-world testing can be injected into these pilot/beta tests, we do believe these pilot/beta tests can inform and precede the real-world interoperability testing as envisioned. The concept of real-world testing would naturally follow such pilot/beta test/early deployment roll-outs to assess capabilities and approach at a larger, cross-organizational level, but before wide, national roll-out.

We note that implementation of an NTC must be practical and not unduly burden participants, particularly considering the complexity of cross-organizational coordination of capabilities and resources. We suggest that adequate funding of specific use cases such as eQMs is provided by the developers and requesters of such eQMs.

## **Responses to Questions**

**1. Please confirm the examples in the background section and identify additional examples of clinical testing needs that could be met with a NTC. How could CDC design and execute a national testbed infrastructure that can support all the clinical testing needs identified? Please consider the importance of an agile development approach in the design and execution of a NTC.**

- a. The synopsis focuses more on the testing of the information technology, and less so on the efficacy of the content (e.g., for CDS the use of applicable/correct evidence). Because individual health IT developers already do extensive testing of their own functionality, the EHR Association recommends that both aspects be addressed for the use case at hand, e.g., CDS or eQm, with a particular focus on testing of content in the NTC.
- b. We advise that there may be multiple test collaborations for the same use case to address variances such as geography, case mix, race/ethnicity, academic/community settings, and/or allow wider participation across smaller more manageable groups.
- c. Real-world interoperability-focused testing for CDS and eQm reporting requires extensive collaboration across key stakeholders, such as: providers, researchers, knowledge/content vendors, and respective IT suppliers on both the sender and

receiver sides. Development and execution of suitable test plans and scenarios require substantial planning, preparation, and participation before the first test can be performed. It is critical to consider the need to iterate through the process, with participation by standards developers and implementers, to rapidly respond to the learnings. Ideally, testing is built into the development process, but the reality is that testing at this scale has not yet been deeply integrated. Evolving experiences with Argonaut and Da Vinci show the promise of such collaborations for real-world testing, and also for integration with the standards and implementation processes.

**2. *Should a phased approach be considered to accommodate all the clinical testing needs? For example, should the initial scope of the testing begin with CDS, eQMs, and a limited number of additional health IT and then expand to more types of health IT?***

- a. EHRA agrees with taking a phased approach that perhaps should start more narrowly, e.g., start with CDS and eQM:
  - i. CDS is a rapidly evolving, fairly new area of cross-organizational deployment with a highly interested group of stakeholders. The opioid crisis and use of PDMPs and supporting knowledge/content/evidence providers could provide substantial value and interest to exercise and demonstrate the value of real-world testing.
  - ii. eQM can address the real challenges of consistently collecting and communicating measure data across venues.
- b. While we recognize the value of progressing both streams at the same time, particularly as CQL is a common thread and there exists the need to approach data use and exchange consistently across both, it should not be required that stakeholders participate in both, in particular health IT suppliers; they may not offer both, and/or may not have the bandwidth to participate in both simultaneously.
- c. The Association suggests that other interoperability use cases be addressed in later phases. In particular, considering the wide variety of public health reporting across states, efforts toward requiring more fundamental alignment of data requirements should be undertaken before a nationwide test collaboration would be effective.

**3. *Should a NTC support testing needs beyond those related to clinical care? If so, what kinds of additional testing needs should it support?***

- a. ONC appears to be chartered to address how to implement real-world testing of interoperability under the 21st Century Cures Act. CDC should coordinate through ONC to address who focuses on what aspects of the real-world testing provisions, so that these initiatives may be harmonized to avoid unnecessary overlap and conflict.

**4. *What types of organizations, expertise, resources, etc. need to be part of the NTC in order for it to be viable, useful, and effective? Please expand on aspects such as organizational size or location, availability of certain resources (e.g., small clinical practices may not have IT teams), and other areas that can affect the ability to implement various kinds of health IT.***

Ideally the NTC should include representation from:

- a. CDS
  - i. Providers - Representation from large health systems, universities, community hospitals, clinics.
  - ii. Research - Representation from research community members outside of hospital/clinical settings, registries.
  - iii. EHR developers - Representation from those integrating CDS into clinical workflows.
  - iv. Depending on use case:
    - 1. PDMP - Representation from self-developed and commercial PDMP developers.
    - 2. Knowledge/Content Vendors - Representation from those making research available.
- b. eCQM
  - i. Providers - Representation from large health systems, universities, community hospitals, clinics.
  - ii. Payers - Representation from public and private payers.
  - iii. Registries/Research - Representation from registries and research institutes requesting quality and measure data.
  - iv. EHR developers - Representation from software developers across the settings calculating quality measures.
  - v. Measure Authors - Representation from organizations developing measures.

**5. *What type of governance model(s) would be needed to operationalize a NTC? Please identify the functions, resources, barriers, facilitators, policies, and other aspects needed in your suggested governance model(s).***

- a. Collaboration by all impacted/benefiting stakeholders is critical.
- b. The collaboration should be open to all interested in participation. The EHR Association believes that participation will be self-selecting based on investment and value, therefore it does not need to be limited.
- c. EHRA suggests that support staff be funded by ONC/CDC, while other participants provide in-kind contributions.

**6. *How can the NTC be developed to be sustainable for the long-term?***

- a. EHRA suggests incenting provider participation through programs such as Promoting Interoperability.
- b. We believe that ongoing funding of support staff by ONC and CDC, perhaps in collaboration with NIST, would be appropriate given the distributed value across the industry, thus not requiring individual contributions beyond in-kind, while maintaining a consistent approach at a national level.
- c. We note that implementation of an NTC must be practical and not unduly burden participants, particularly considering the complexity of cross-organizational coordination

of capabilities and resources. We suggest that adequate funding of specific use cases such as eCQMs is provided by the developers and requesters of such eCQMs.

**7. What would a successful NTC look like? What kinds of metrics should be tracked to evaluate this success (e.g., return on investment (ROI) or other endpoints)?**

- a. Potential metrics that would be indicative of success include:
  - i. Participation level in real-world testing infrastructure - A majority of EHR developers participate.
  - ii. Adoption of the resulting standards/content throughout the industry - Trending up/High.
  - iii. Friction to adopt by >95 percent of providers - Trending down/Low.
  - iv. Impact on clinical outcomes for CDS - Trending up/High.
  - v. Impact on reporting quality for eCQMs - Trending up/High.
  - vi. Additional clinical documentation burden - Trending down/Low.

**8. Are there any additional considerations for a national testbed infrastructure that were not captured in the previous questions? If so, please identify them and provide supporting information on (a) why those items should be included, (b) what types of organizations and resources would be needed to support those items, (c) what the downside would be if they were not included.**

- a. The Association believes we addressed these opportunities in the prior questions.

The EHR Association and its members strongly believe in the power of health information and technology to support safe and high quality healthcare, and we thank you for this opportunity to comment.

Sincerely,



Cherie Holmes-Henry  
Chair, EHR Association  
NextGen Healthcare



Sasha TerMaat  
Vice Chair, EHR Association  
Epic

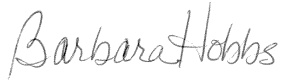
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#### **About the EHR Association**

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit [www.ehra.org](http://www.ehra.org).