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Submitted electronically at: http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments

Re: A Shared Nationwide Interoperability Roadmap DRAFT version 1.0

Dear Dr. DeSalvo,

On behalf of Epic, an electronic health records developer based in Verona, Wisconsin, we appreciate this opportunity to formally comment on Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap DRAFT version 1.0. Epic's commitment to interoperability is demonstrated by the success of our users. Organizations using Care Everywhere, Epic's interoperability platform, make up the largest EHR exchange group in the United States, exchanging nearly 8.5 million patient records a month with each other and with about 7,500 other organizations. This includes healthcare providers using other EHR systems, health information service providers, health information exchanges, and entities connected to the eHealth Exchange like the Veteran's Administration, the Social Security Administration, and the Department of Defense.

Use Cases

You requested that we submit priority uses cases from Appendix H. The list of use cases includes a wide range of examples at varying levels of granularity. We suggest the following two important areas to focus on first:

1. ***Whenever a patient sees a provider, their record is available.*** As patients, we want our records to be accessible to our doctors, whether our visits are planned or unexpected. Accommodating both planned and unplanned transitions of care should be a priority use case.
2. ***Bi-directional exchange with public health agencies.***

Focus on these two is an urgent national priority and should be maintained until measurement shows widespread national success. Technology is going to continue to evolve over time, so selected use cases and measurements should ideally be outcome-focused and technology-neutral.

A. Shared governance of policy and standards that enable interoperability

Our experience does show that having a single, simple rules of the road for exchanging information for treatment effectively and rapidly advances interoperability in the healthcare industry. Work on a simple set of rules to cross networks is a priority, and is one of the reasons that we were a founding member of Carequality, which aims to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, or a state HIE, to interoperate freely with one another.

ONC has suggested prioritizing the interoperability of a common clinical data set for purposes of treatment (Critical Action A1.1). We agree that this is an area of focus that is a high priority to healthcare providers and patients, and it will benefit from extensive existing work on appropriate standards and current exchange.

C. Individuals are empowered to be active managers of their health

One area of challenge for engaging patients is with proxy access to information, such as parents acting as proxies for children. Clear guidance for healthcare organizations could accelerate work in this area. ONC could convene policy makers to offer model policy for states that do not take electronic access to information into account or by offering clarity around proxy requirements and opportunities, for example, by not requiring wet signatures or legal guardianship, and by collecting and standardizing requirements around minors.

Regarding advance directives, an important first step for the industry would be to formalize an appropriate standard for the transmission of advance directives. These documents have a unique challenge in that having the most recent advance directive is critical. For example, if a patient changes her mind about a Do Not Resuscitate decision, this change needs to get to all organizations that have a copy of the patient's advance directive.

D. Care providers partner with individuals to deliver high value care

In call to action D4.1, several actions are included in the 2015-2017 timeframe. However, our experience is that these workflows have widely varying levels of standards maturity and adoption. For example, e-prescribing is standardized and widely used across the country, while PDMP drug monitoring systems are not standardized and have significant variance across databases. Each workflow should be evaluated against the current state for consideration on an appropriate timeframe.

E. Ubiquitous, secure network infrastructure

In line with ONC's guiding principle of "one size does not fit all," as ONC develops a cybersecurity encryption policy, the policy should allow flexibility for organizations to tailor the security measures to best match the architectures of their systems.

E2 proposes to develop "at rest" standards and potential guidance for data encryption. These standards and guidance will want to differentiate the effectiveness of encryption of different media against common security risks. Encryption of devices that are often lost or stolen, such as laptops or mobile device, is an effective strategy. Encryption of servers in a secure data center, that are unlikely to be physically stolen, would offer less protection than comparable investments to avoid intrusion with trusted credentials (spear phishing).

F. Verifiable identity and authentication of all participants

As work is done on F1 to adopt policies using multi-factor authentication for all roles to access health information, the workflow burden of available multi-factor authentication options on clinicians who might be authenticating to a system dozens or hundreds of a times a day will need to be carefully considered.

G. Consistent representation of permission to collect, share and use identifiable health information

We agree that ONC focus the majority of their efforts on education and outreach.

For the proposal "to advance individuals' rights to make choices about the use and disclosure of their electronic health information," we are concerned that allowing patients the ability to selectively share their clinical information may, without careful oversight, lead to unintended consequences.

- First, patients may not understand the potential health implications of suppressing certain kinds of data, such as redacting medications that produce deadly side effects when combined with other common medications.
- Second, documentation in an EHR is significantly complex, and patients who intend to suppress a certain condition may not realize that any trained clinician could recognize the condition, based on the patient's notes, lab results, lab orders, and a pattern of visits and consults.

When a trained clinician makes this inference, a patient may feel betrayed by the assurance that such data was to be kept confidential. Organizations that use Epic have told us that patients, when given a simple binary choice to share or not share data, overwhelmingly decide to share their data. Simple choices help align patient expectations with reality. Patients not understanding the ramifications of their choices could result in patient safety issues or a loss of trust in clinical environments. We recommend a simple opt-in/opt-out approach.

H. Consistent representation of authorization to access health information

During your planned listening sessions, we suggest you consider Organized Healthcare Arrangements (OHCAs), ACOs, or other similar arrangements where multiple covered entities share the same patient record. Multiple covered entities sharing the same record can align policies regarding authorization just as they do regarding HIPAA; authorization policies should be flexible enough to accommodate this alignment.

I. Stakeholder assurance that health IT is interoperable

We've listed here several suggestions for how the current NIST testing tools for certification could be made more helpful to EHR developers in creating robustly interoperable software:

- Support bulk validation. The current NIST testing tools validate only a single message at a time, and a tester has to copy and paste the message or select the message.
- Provide publicly available validation web services that don't require human intervention so that health IT developers can implement them during the development and testing period, allowing each generated message to be evaluated quickly and efficiently.
- Ensure that the tools are consistently available without unpredictable downtimes.
- Release the tools at a state of high quality so there is not confusion about whether the tools themselves have errors in the certification process or there is an issue with the software.

J. Consistent Data Formats and Semantics

Epic recommends that this Roadmap not focus on specific standards or technological approaches but instead give a high-level direction. Specific standards references should be handled by the 2015 Interoperability Standards Advisory.

K. Standard, secure services

By definition, APIs are program- and technology solution-specific. In order to make general APIs that support interoperability, the industry needs standards. Epic continues to work with standards organizations to create both standards and profiles that define the technology and content specifications for exchanging data with systems. We believe that by adopting standardized APIs like IHE profiles and FHIR resources, health IT technology developers and organizations are implementing APIs that can be used broadly and easily for interoperability. We urge ONC to continue to look to existing standards development efforts to reduce complexity and promote reusability across the industry.

L. Consistent, secure transport technique(s)

Consider merging the ability to Send (Critical Action L2) and the ability to Receive (Critical Action L3) as effective standards work will define both end points of a transaction.

M. Accurate identity matching

Section M proposes data elements that should be used as a starting point for standardization of demographic data. AHIMA has researched this area and published a paper entitled "Patient Matching in Health Information Exchanges." We recommend that ONC align their work with the work that AHIMA has already done to help support accurate identity matching.

Coordinated governance is suggested in several of the critical actions for this section. Market forces and interest in better match rates will drive testing and adoption of new voluntary data elements; coordinated governance is not necessary in this area. A helpful role for governance would be to ensure that other requirements do not inhibit testing and experimentation with voluntary data elements and strategies to improve match rates.

In regards to M1.4, existing protocols such as XCPD, PIX, and PDQ already define APIs for patient matching and are being successfully used on a national level, such as by the eHealth Exchange, so we are uncertain what this step suggests.

N. Reliable resource location

Standards for provider directories should encompass both real-time and bulk queries. Real-time queries might not perform quickly enough when interoperability is integrated into a provider's workflow. Bulk queries would allow directories to be periodically updated or requested in advance of an appointment and locally stored to avoid any delays for clinicians.

Tracking Progress and Measuring Success

We agree that metrics are necessary to track the progress of interoperability within the industry. Carefully selected objective metrics must take advantage of existing data sources and not require deviation from existing provider workflows. Measurement should be narrowed down to 3-5 metrics to be effective and meaningful.

Thank you for your consideration.

Sincerely,

Peter DeVault
Epic