American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

February 15, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Draft Trusted Exchange Framework and Common Agreement

Dear Dr. Rucker:

On behalf of our nearly 5,000 member hospitals, health systems, and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the draft Trusted Exchange Framework and Common Agreement released Jan. 5 by the Office of the National Coordinator for Health Information (ONC). We submitted a separate letter on the draft U.S. Core Data for Interoperability document that also includes our comments on approaches for connecting prescription drug monitoring programs.

The AHA applauds ONC for pursuing a voluntary "network of networks" approach that aims to simplify the process of health information exchange for hospitals and health systems and increase transparency about exchange entities. We also agree with the need to build on existing efforts. However, we recommend that ONC carefully consider how best to scale and stage the effort to allow broad participation. The agency also could do more to ensure alignment with the Health Insurance Portability and Accountability Act's (HIPAA) requirements for covered entities, such as specifying the obligations of those making requests for information. Furthermore, ONC must ensure that the recognized coordinating entity, which will provide oversight and governance for the nationwide exchange, is independent. The recognized coordinating entity should be governed by those participating in the exchange, with majority representation from the end-user community, such as hospitals and health systems, other health care organizations, clinicians and consumers.

Our detailed comments follow.

AMERICAN HOSPITAL ASSOCIATION
NISI DOMINUS FRUSTRA
FOUNDED 1898

BACKGROUND

The draft Trusted Exchange Framework and Common Agreement describes a set of legal relationships, governance approaches and types of information exchange that would allow for more efficient and effective sharing of health information across the country. Specifically, the document puts forward six principles and more than 100 minimum required terms and conditions that would apply to those entities that voluntarily choose to share information under the trusted exchange framework. It also creates a structure for trusted information exchange that comprises:

- A single recognized coordinating entity selected by ONC to govern, operationalize and enforce the trusted exchange framework through a common agreement. The recognized coordinating entity also would consult with stakeholders to update processes, agreements, and use cases over time.

- Multiple qualified health information networks (QHINs) that would connect directly to each other and would serve as the core infrastructure for nationwide interoperability.

- Multiple health information networks (HINs) that would connect to the QHINs and whose participants would share information through the network of networks created under the Trusted Exchange Framework and Common Agreement.

- Participants and end-users of the HINs that would be required to comply with the terms of the Trusted Exchange Framework and Common Agreement through participant agreements with the HINs and QHINs.

The draft also sets forward six "permitted purposes" for information exchange – treatment, payment, health care operations, public health, individual access to health information, and benefits determination (specific to determining eligibility for disability benefits under the Department of Veterans Affairs and Social Security Administration). It then describes three "use cases," which represent the ways in which exchange may happen and include: a broadcast query to all participants in the exchange asking for information about a specific individual(s); a directed query to a specific organization(s); and population level data requesting information about multiple individuals in a single query (with no upper bound provided). The draft document would require all QHINs, HINs and participants to support all six permitted purposes and all three use cases if they wanted to be part of the Trusted Exchange Framework.

OVERALL STRUCTURE

The AHA applauds ONC for pursuing a voluntary "network of networks" approach that aims to simplify the process of health information exchange for hospitals, health systems and other entities. The use of a network-of-network approach that is based on a single set of rules and builds on existing initiatives promises to create efficiency. Hospitals and health systems would greatly benefit from an approach that allows "a single on-ramp" for the exchange, where one network serves as a gateway to sharing information across the entire exchange infrastructure. The overall direction is appropriate and consistent with the objectives of the 21st

Century Cures Act. As noted in the document, hospitals today must make use of many different health information networks as well as creating one-off connections and interfaces to accomplish their information sharing needs. This arduous approach creates cost and complexity, and significantly limits the extent of information sharing. Building the infrastructure to share information efficiently and effectively will pay dividends in improved care coordination, increased patient engagement in health and increased value.

The AHA strongly supports the transparency provisions in the draft document. We welcome the requirement for QHINs to make their privacy practices easily available and to charge only reasonable allowable costs for onboarding and testing. We request clarification as to whether these transparency requirements on privacy practices and reasonable costs also pertain to HINs.

The AHA agrees with the stated goal of building on existing efforts. Building on existing initiatives should allow all parties to continue to realize value from existing investments and arrangements, while building new capacities. However, these advantages will only be realized if there is a realistic pathway from current capabilities to the future state.

ENSURING BROAD PARTICIPATION

The AHA recommends that ONC carefully consider how best to scale and stage the Trusted Exchanged Framework and Common Agreement to ensure broad participation. Given that participation in trusted exchange is voluntary, it will be important to pursue a realistic pathway, so that participation is robust and the ecosystem can continue to develop over time through actual use. Allowing early participants to succeed in exchanging at least some data will build momentum and increase the value of sharing as more participants join in. A staged approach also may be more consistent with statutory intent. The 21st Century Cures Act requires that the approach adopted by ONC "avoid the disruption of existing exchanges between participants of health information networks (Sec. 4003(b)(9)(F)(iii))."

In particular, the all-or-nothing approach that requires all participants to support all six permitted purposes and all three use cases is counter-productive and will limit participation. That approach also breaks with ONC's principle of building on existing efforts, since few, if any networks in use today could fulfill all of those roles without significant effort. For example, not all HINs, participants and end-users may be able to support benefits determination or population-level (batch) data from the beginning. It is unclear how much effort and time would be required to build those capabilities, but it would certainly delay the availability of the network of networks that could enable more efficient, nationwide exchange if entities could not participate until all of those functionalities were supported.

For their part, hospitals, health systems and other health care providers would need to undertake significant changes to their own information technology systems and operations in order to engage in the full set of activities described. There will be significant cost and work associated with participation, including revisions to internal policies and capabilities associated with fulfilling the permitted purposes and adding any new or additional exchange partners. The provider community also would need to revise existing information exchange agreements,

business associate agreements and patient consent approaches. The financial resources and staff time needed to make all of those changes simultaneously may make participation in the Trusted Exchange Framework unrealistic, resulting in diminished overall information exchange than might be achieved with greater flexibility and a staged approach. In addition, the ability for providers to participate will be very dependent on what electronic health records (EHRs) will support. It is unclear from the document whether ONC intends to use certification to ensure that the capabilities necessary to participate in exchange will be available in certified products. We would appreciate additional clarification on this point.

Therefore, a successful start may require more flexibility to build from existing exchange capability and a phasing in of the more ambitious permitted purposes and use cases supported, based on the results of pilot testing. Individual participants and end-users could have the option to engage only in the types of exchange they are able to support, at least at the beginning. As experience builds, additional capabilities could be added. Specifically, ONC might consider starting with what can be widely accomplished today, and build up to other types of exchange. For example, current capabilities most widely support exchange of summary of care documents for individuals. A focus on scaling that type of exchange would be a reasonable starting place to build broad participation. Other use cases, such as sharing individual data elements through use of application programming interfaces (APIs), or sharing data on large groups of individuals in a batch transfer (the population health use case), could be built into the nationwide infrastructure over time, after completion of pilot tests to ensure the approaches work. Additional purposes, such as research, also could be added over time. This staged approach is consistent with the 21st Century Cures Act, which states that the "National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement (Sec. 4003(b)(9)(B)(iii))."

Furthermore, it is unclear whether standards are fully mature to support all of the permitted purposes and use cases described. Before something is required, it must be mature, accompanied by specific implementation guidance, pilot tested and shown to have value in actual use that is greater than the effort required to put it in place. For example, APIs are a positive development, but standards are still maturing. The Fast Healthcare Information Resource (FHIR) standard is very promising, but still evolving, which means that APIs are not yet standardized. Indeed, while the 2015 Edition Certification requirements include enabling an API in certified EHR technology, it does not require the use of any given standard. In addition, the FHIR standard only facilitates the sharing of data elements, and does not address whether we have a common understanding of what the shared data mean (semantic interoperability). Moreover, the entire ecosystem will need some ability to validate that "apps" are secure and conform with existing privacy laws. It is unclear from the document what type of vetting process would be deployed to provide assurances of this type.

Similarly, the standards and processes for initiating, receiving and responding to population health, or batch requests for data have not been systematically considered through a consensus process. For example, the community has yet to contemplate what types of information would need to accompany such a request to allow the responding organizations to be sure that they are responding "to the extent permitted under Applicable Law," without violating those same laws.

This issue is examined in more detail below. As another example, the lack of a national solution to the patient matching problem could introduce tremendous uncertainty into the accuracy of data exchanged in a batch manner. How will those challenges be mitigated? What is an acceptable level of mismatch? Does that vary according to the use of the data? While the draft directs participants in the exchange to use a specified set of demographic data to enable patient matching, it does not speak to these more challenging issues. Addressing them, however, is fundamental to creating trust in the accuracy of the data exchanged.

To ensure feasibility of new types of information exchange over time, ONC could consider chartering the recognized coordinating entity to follow a more specific use case approach that allows more granular description of the data that are needed for a specified purpose and the standards and implementation specifications that will apply. For example, what are the data fields that are most important for the exchange of radiology tests, which standards support that exchange, and are they mature enough to support exchange on a nationwide scale? Have they been pilot tested and shown to work? Do these exchanges meet a priority need in production and provide value greater than their costs? Once these questions have been answered in the affirmative, that use case could be rolled out across exchanges.

ALIGNMENT WITH HIPAA REQUIREMENTS

The document seemingly wants to both hold HIPAA-covered entities responsible for complying with HIPAA and provide a different, and possibly conflicting, set of information sharing, privacy and security responsibilities for other, non-covered participants in the exchange. This uneven treatment could put HIPAA-covered entities in a very challenging situation.

For example, the outer limits for providing breach notification are different from HIPAA and require a shorter notification timeframe of 15 days. This disparity will create a challenge for covered entities, who have developed processes and response plans based on the HIPAA rules. **We recommend aligning the breach notification requirements with HIPAA. ONC also should clarify that notification should be made upon determination that a breach has occurred, not when a breach is suspected.**

In addition, end-users and participants are expected to respond to all requests for information under the six permitted purposes, but covered entities also must meet their HIPAA obligations to maintain business associate agreements and exchange only the minimum necessary information needed to fulfill the purpose of a disclosure. **Indeed, the obligations of those who receive a request for information are specified in considerable detail in the document, but there is little discussion of the obligations of those who make a request.** How would requestors communicate the purpose of their request, such as being a fellow participant in an accountable care organization, so that a covered-entity respondent can judge whether responding to the request meets HIPAA requirements? What are the guardrails for reasonable requests that would ensure that the request is only to share minimum necessary information that a covered entity is permitted to disclose?

The framework document also specifies that failure to respond to a request for information can constitute and be reported as a possible instance of information blocking. However, HIPAA-

covered entities may not be able to respond to a query if there is insufficient information to determine whether information can be shared, or if the request cannot be filled due to the limitations imposed by HIPAA. This assumption of information blocking risks generating many complaints that HIPAA-covered entities are engaging in information blocking, when in fact they are merely trying to comply with their legal obligations to use and disclose information as only permitted by the rule.

As currently envisioned, the framework holds covered entities responsible for complying with HIPAA, but provides no mechanism to ensure that any request for disclosure provides sufficient information to help the covered entity know whether they are permitted to make the disclosure under the rule. Furthermore, there is nothing that guarantees that non-covered entities can only make appropriate requests for minimum necessary information, assuming a covered entity is even permitted to give them access to protected health information (PHI) under the HIPAA rules. It may be necessary to add "meta-data" to a request that speaks to concerns like the purpose of the request and allows the responding covered entity to determine how to fulfill its obligations under HIPAA to guarantee use and disclosure of PHI only as permissible under the rule. Alternatively, ONC could specify that all entities participating in the Trusted Exchange Framework and Common Agreement will abide by the requirements of HIPAA, whether they are HIPAA-covered entities or not.

While this discussion has focused on compliance with HIPAA, similar concerns arise with state and local privacy and security laws. Without harmonization of those varying requirements, or the inclusion of information about the purpose of requests and the entity requesting information, it will be very challenging, if not impossible to know whether responding to a specific request is, in fact, allowed by applicable law.

ATTRIBUTES OF THE RECOGNIZED COORDINATING ENTITY

The recognized coordinating entity will play very important operations, enforcement, governance and strategic roles. It must, therefore, be carefully considered to ensure independence and fairness. First, the recognized coordinating entity must have very transparent governance that engages all stakeholders, and particularly end-users. There must be representation of all stakeholders in the recognized coordinating entity's own governance process, with the majority of its board or advisory group coming from end-users of the trusted exchange ecosystem (such as consumers, hospitals and health systems, and clinicians). This approach will ensure that future efforts are driven by high-priority needs that improve patient engagement, care coordination, and the quality of care provided.

Second, federal involvement and support will be crucial to ensuring progress on trusted exchange, not least because many federal entities create and share health information. That said, the recognized coordinating entity also must be financially sustainable and not overly dependent on federal funding. It must have considerable independence from the federal government and have the ability to establish a predictable roadmap that QHINs, HINs, participants and end-users can use to map their own investments in information exchange capabilities. The government should not have the ability to unilaterally change that roadmap.

Given these necessary attributes, a cooperative agreement may not be the most appropriate vehicle for the RCE, as it has limited transparency and elevates the role of ONC compared to the role of the participants in the exchange. If a cooperative agreement is used, however, the scope of work should be transparent to all stakeholders and a public vetting process should be followed to ensure any change to the scope of work meets stakeholder needs.

ADDITIONAL CONCERNS

In addition to the broad areas discussed above, the AHA has concerns about the following specific areas:

- The Trusted Exchange Framework will need to clarify how de-duplication of response data will happen. If a request is made, will multiple QHINs all provide the same data back to the requestor? How will duplicate data be handled?

- It appears that ONC intends to have organizations authenticate and provide credentials for specific individuals within their organizations to share data. The Trusted Exchange Framework also should allow organization-level authentication and credentialing to reduce burden.

- The draft document would require QHINs to collect and maintain copies of patient consent, which could be a challenge to operationalize. For example, how will participants share copies of patient consent with QHINs, and how will QHINs manage those documents?

- The draft document points to a requirement for two-factor authentication among all participants. This approach could provide quite challenging to small and rural hospitals, with limited ability to implement these approaches.

In closing, we appreciate the opportunity to provide comment on the vital work to improve the efficiency of health information exchange. The AHA stands ready to be a resource to ONC as it continues to refine the approach and develop the Trusted Exchange Framework and Common Agreement. If you have any questions or need additional assistance, please contact me or have a member of your team contact Chantal Worzala, vice president, health information and policy operations, at cworzala@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy