AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

February 20, 2018

VIA ELECTRONIC MAIL
exchangeframework@hhs.gov

Donald Rucker, MD
National Coordinator
Office of National Coordinator for Health Information Technology (ONC)

Re: Trusted Exchange Framework and Common Agreement

Dear Mr. Rucker,

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Office of National Coordinator for Health Information Technology (ONC) proposed Trusted Exchange Framework and Common Agreement (TEFCA). Our organization is the policy voice for five Seventh-day Adventist affiliated health systems that include 83 hospitals and more than 300 other health facilities in 17 states and the District of Columbia.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. With such diverse facilities, populations served and geographical locations, we strive to provide an objective and sound policy voice. Below, please find AHPA's general comments on interoperability and specific recommendations on TEFCA. Specifically, we comment on the following principles proposed in the TEFCA.

- Standardization
- Transparency
- Cooperation and Non-Discrimination
- Privacy, Security and Safety
- Data-driven Accountability

AHPA's Ideal State for National Interoperability

AHPA believes that efforts to achieve interoperability should be centered on the patient. As patients navigate throughout the continuum of care—through physician offices, hospitals, same-day surgery centers, or community clinics—their records should be easily transferrable between all organizations. In an ideal state of interoperability, patients would not be placed under the burden of having to seek their medical records from different providers.

One of the greatest challenges to achieve this level of interoperability is the lack of a single patient identifier that can move from system to system and ensure records can be passed between disparate entities without fail. The lack of a national patient identifier makes it difficult for data to be exchanged seamlessly between organizations. Regardless of the electronic system, there will always be variability in the registration and data entry processes at each organization. This will prevent the health care industry from achieving full positive identity matching.

As the health care industry shifts towards value-based care, it will also be critical for hospitals and Integrated Delivery Networks (IDNs) to be able to easily communicate with community providers and clinics in a cost-effective manner. This connectivity needs to be standard for entities that do not have the financial or technical means to connect to a large national Health Information Exchange. The vendors supporting these community providers should remove the technological and financial barriers impeding their ability to achieve interoperability. AHPA believes that this is crucial to ensure adequate care coordination.

Standardization: Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.

AHPA believes that all stakeholders engaged in data sharing should be required to provide a minimum set of data elements approved by the standards agency. These data elements should include all clinical elements needed for providers to establish an accurate and comprehensive clinical picture of the patient. In addition to the clinical data, AHPA recommends that CMS develop a standard format for the sharing of financial and administrative data.

While using open source tools, such as the ONC's C-CDA has been helpful, providers are often unable to obtain the necessary data classes to establish an appropriate clinical picture of the patient. The information sent by stakeholders may not provide a computer readable version of the data in a consistent nomenclature. It is our belief that if specified data classes were required to be exchanged (not just list those that should be able to be supported), that would lead to more meaningful sharing of patient records between systems. To help with adoption, we recommend that the ONC require vendors to support and build systems capable of capturing and sharing the specified data classes. Additionally, the ONC should require the use of a specific nomenclature for data classes. These changes would help drive conformance to a standard across the country.

Transparency: Conduct all exchanges openly and transparently.

AHPA recommends that all the permitted purposes for which a network may be used to exchange data, follow the existing treatment, payment and operations protocols for using or disclosing Electronic Health Information.

Today, participation agreements are custom by state and entity. Having a common framework for participation agreements would cut down on time to onboard and allow for a single "on-ramp" to interoperability. AHPA recommends considering the e-Health Participation Agreement for a national contracting standard, with exhibits for any state and entity specifications. This will provide the needed balance between state/entity flexibility and national standardization.

Privacy, Security, and Safety: Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity.

The greatest interoperability barrier currently faced by the country is the inability to accurately match patients between health care systems and Health Information Networks (HINs). To be able to coordinate care and share relevant clinical documentation, HINs must be confident that they are exchanging data about the same person. Current standards, whether C-CDA or FHIR, do not go far enough in enabling this type of matching. To address this issue, AHPA recommends the use of a national patient index with national patient identifiers to facilitate patient matching and interoperability. If a national index proves too difficult to achieve in the short term, then we recommend requiring a common probabilistic matching algorithm to identify patient matching for HINs and providing guidance on thresholds for creating a positive match. This requirement would standardize which demographics health care systems and vendors must capture for relevant matching criteria. As currently written, the proposed TEFCA does not address this interoperability barrier.

The second largest barrier to nationwide interoperability is the lack of a common consent model and an agreement on the definition of super sensitive data. To facilitate the appropriate access, use, and disclosure of Electronic Protected Health Information, AHPA recommends that the ONC standardize consent models across states and health care settings. Until electronic medical record software vendors can create an Electronic Health Record (EHR) that can attach consent values to each data element, AHPA recommends requiring providers to request written patient authorization for the access, use, and disclosure of a patient's Electronic Protected Health Information from any source, or allowing a patient to specify which provider sources of Electronic Protected Health Information the requesting provider may access, use, or disclose. The state of Florida Health Information Exchange has created a good example of this authorization, which is set forth in the Universal Patient Authorization forms for Full or Limited Disclosure.[1] This interim solution would satisfy the state law obligations for obtaining consent for super sensitive data as well as the federal substance abuse laws, and would allow patients to decide which providers can access their Electronic Protected Health Information from all sources. If implemented, this interim solution should also provide immunity to providers from patients claiming that the consent was not valid and create a protection for providers when excluded from a patient's Electronic Protected Health Information. Having a greater focus on standardizing consents and moving towards EHRs that have the technical capability to attach consent values to each data element will help ensure that a patient's privacy is properly guaranteed.

Data-driven Accountability: Exchange multiple records for a cohort of patients at one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.

AHPA believes that Population Level requests for sharing data are important to attain improved patient outcomes and lower costs. However, we ask that the ONC provide a clearer definition around the bulk pull mechanism that would enable the exchange of multiple patient records at one time. Without a clear

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[1] Florida's Health Information Exchange forms can be found at: http://www.fhin.net/privacyRegulations/docs/PatientAuthorizationRule.pdf

guideline or too much optionality, Health Information Technology (HIT) vendors will create an array of capabilities all claiming to meet a standard but unable to interoperate and share Population Level data.

Additionally, AHPA believes that the ONC should recommend a set of industry-wide population health quality measures to ensure standardization in the exchange of data. Vendors currently do not share a common standard for capturing or exchanging population health data, as well as a population health data layout. To support the exchange of multiple records for a cohort of patients at one time, vendors would need to support a standard data gathering method, a standard population health data layout, and a common export mechanism for population health data and quality measures.

Lastly, we recommend that the ONC require any requestor of Population Level data to be able to legally prove that they have patient authorization from all the patients in the entire cohort or are legally permitted to obtain this data under Applicable Law without patient authorization, before receiving the bulk exchange of data in batch mode. This will help assure that the requestor has the appropriate legal rights to obtain the data. We believe this mechanism needs be scalable to address bulk or cohort exchanges.

Additional Comments on the TEFCA:

Below are additional comments in response to the ONC’s request for input on the following items:

Are there particular eligibility requirements for the Recognized Coordinating Entity (RCE) that ONC should consider when developing the Cooperative Agreement?

AHPA recommends that the ONC consider the following eligibility requirements for the RCEs: experience with interoperability standards, implementation experience with interoperability projects and an in-depth knowledge of the health care industry. This includes knowledge of hospitals, long-term care facilities, physician offices and community clinics.

Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?

AHPA recommends the use of a national patient index to facilitate patient matching. If developing a national index proves to be too difficult, then the ONC should require a common probabilistic matching algorithm to identify individuals. This algorithm should be common among the HINs, along with the required data elements and accepted thresholds for matching patients.

How can a single “on-ramp” to important health data (i.e. Prescription Drug Monitoring Program (PDMP) data) work regardless of the HIN?

Today, providers already perform medication reconciliation and EHRs already pull data from SureScripts and other sources as part of this medication reconciliation process. Expecting HINs to also help in this medication reconciliation process seems duplicative.

How should interstate connectivity for PDMP data be addressed given the variation of state laws and urgency of the opioid epidemic?

Interstate connectivity for PDMP data can be accomplished by having standardized record sharing and patient matching technologies. A query and response-based network would also need to be built on top of state-level opioid registries to ensure adequate connectivity. Most importantly, we recommend the development of a national designation or definition of opioids, instead of the current state-specific designations. We believe this is necessary to prevent the violation of any state laws.

How can the Framework incorporate existing entities currently addressing opioid use and support the technical capabilities (as opposed to the applicable organizational requirements) for PDMPs?

We believe that the Framework needs to be backward compatible with the platforms in use today for opioid monitoring and data mining. Providers also need to know when to share opioid information with providers who had a past relationship with the patient. Legal clarity on the rules governing the exchange of opioid-related patient information across states must also be provided to ensure compliance with different state laws.

How can the Framework best comply with the NIST SP 800-171, which imposes requirements on nonfederal information systems and organizations to protect Controlled Unclassified Information (CUI) when a federal agency's mission requires that it disseminates the information?

The framework will need to honor the patient consent wishes and abide by the existing state supported consent practices and protections.

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback-Aldinger, Director of AHPA, at Julie.Zaiback@ahss.org.

Sincerely,

Jeff Bromme
President