American College of Physicians
Leading Internal Medicine, Improving Lives

June 17, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

Re: Comments on the Draft Trusted Exchange Framework and Common Agreement Draft 2

Dear Dr. Rucker,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the National Coordinator for Health Information Technology's (ONC's) Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP welcomes ONC's continued commitment to developing the policies, procedures, and technical framework to facilitate secure, seamless, and sustainable health information exchange to improve care across the entire care continuum. Effective, practical, and secure interoperability is crucial to improving the patient experience and the patient-physician relationship, reducing burden on physicians, and in turn improving the quality of care.

ONC has made many important and necessary changes that improve upon the first draft of TEFCA, and while the second draft framework and agreement move the industry closer to improved health information exchange, the College has unresolved concerns. First, having just submitted our public comments on ONC's information blocking proposed regulation, we would like to reiterate our concerns around the approach to information blocking enforcement and possible conflicts with protecting patient privacy. The push to improve access and seamless exchange and use of health data is critical to improving health care in the US, and TEFCA will undoubtedly be a key element. However, the current approach to opening the floodgates for

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exchange of sensitive data, layered with complicated information blocking provisions and exceptions, places clinicians in the middle of a complicated process to exchange data while striving to protect their patients and maintain their trust. Moreover, the College believes that current efforts to improve interoperability, including TEFCA Draft 2, still do not focus on the types of health information exchange needed for useful clinical management of patients as they transition through the health care system. Patients and clinicians need seamless exchange of valuable, meaningful data at the point of care, the ability to incorporate clinical perspective and query health IT systems for up-to-date information related to specific, relevant clinical questions. Therefore, we provide comments regarding the applicability and usefulness of the proposed exchange modalities for physicians and other clinicians, feasibility of the implementation timeline for clinicians, amongst other areas of improvement.

The College appreciates the opportunity to provide feedback on the TEFCA Draft 2 and offers the following comments and priority recommendations in the sections below.

Creating a Single "On-Ramp"

Central to the framework laid out in the draft, ONC proposes establishing a single on-ramp, or a uniform mechanism to connect, for all users and uses of the network. The College strongly supports the goal of minimizing the number of connections a participant or clinician would have to implement and use. However, we have concerns that ONC's proposal for a "single on-ramp" to electronic health information (EHI) is not entirely feasible nor is it necessarily always the best and most efficient model for achieving the end goal. It is unrealistic to expect one interface, or "on-ramp," to properly support all of the variations in data exchange or various applications (e.g., Health Information Networks (HINs), Direct messaging, e-Prescribing, Performance Measurement, Public Health Reporting, billing operations, etc.) necessary for true, practical interoperability. For example, e-prescribing is a complex transaction system that would not work as well if it had to use a general-purpose portal or interface. **Therefore, ACP reiterates our comments on Draft 1 that attempts to minimize the complexity and cost for patients and clinicians to exchange health data through a single on-ramp onto the network should be balanced with appropriate variation based on the requirements of each major use of the network.**

TEFCA Structure

The College strongly supports the principles outlined in TEF and believe they are instrumental in developing the technical requirements necessary for accessing, exchanging, and using relevant EHI contained within the Common Agreement (CA) and Qualified Health Information Network Technical Framework (QTF). We applaud ONC for developing a single minimum set of rules from which to operate, while building on existing initiatives and incorporating private sector consensus standards and a private sector Recognized Coordinating Entity (RCE). ACP also commends ONC for addressing concerns raised in our comments on the previous draft, where we urged ONC to remove any technical specifications from the CA and include only the principles that are enduring as opposed to technical specifications that evolve and change over time. ONC proposes moving the technical recommendations to a new appendix—the QTF—

which the RCE will be responsible for updating and maintaining. The QTF will cover things like identity proofing and authentication and utilization of Connectivity Services. **Regarding the QTF, ACP suggests that ONC specify the format in which EHI will be delivered—whether in bulk, organized into sections, etc.—and clarify whether it will be searchable.**

In the second draft, ONC also proposes requiring non-Health Insurance Portability and Accountability Act of 1996 (HIPAA) entities, like third-party app developers, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. ONC contends this requirement will help address some of the current cybersecurity threats by increasing data integrity, confidentiality, and security**. ACP supports this proposal and agrees that requiring stakeholders to comply with privacy and security requirements like HIPAA will bolster confidence amongst participants that shared data is adequately protected and further preserve the trust and confidentiality of the patient-physician relationship.** There have been multiple reports of app developers selling patient data to third parties, not sharing their privacy policies with patients, or failing to adhere to their published privacy policies. Personal health information is some of the most sensitive and private information for an individual. Without the necessary privacy and security controls, it is critical to acknowledge the very real risk present that may ultimately affect the patient's inclination to share information with their physician.

Key Use Cases

Draft 1 of the TEF established three different use cases for exchanging EHI that QHINs would be required to support: Targeted Query, Broadcast Query, and Population-Level Data Exchange. Based on feedback from the previous comment period, ONC determined that the Population-Level Data Exchange use case was not yet mature enough to use and removed it from the Minimum Required Terms and Conditions (MRTC) in the second draft. This use case has been replaced with the addition of the QHIN Message Delivery, which is a "push-based" exchange where a QHIN transmit EHI to another QHIN(s). While ONC outlines the need for QHINs to be able to support these exchange modalities, they do not elaborate on the specifics of what those exchanges would look like in practice and ACP is concerned that each QHIN could implement these modalities differently.

We are further concerned that these proposed exchange modalities continue to focus on identifying and transferring large quantities of clinical data from one location to another. There may be value in these functionalities for some stakeholders; however, they are not the use cases that will address the issues that physicians face in sharing and obtaining EHI. Physicians and other clinicians need immediate access to accurate information at the point of care to make proper health determinations and communicate effectively with patients and other clinicians. **Hence, the College recommends expanding the exchange modalities in the QTF to allow for more specific use cases, such as a physician in the inpatient hospital requesting just the most recent medical prescriptions from the primary care physician.**

Physicians must have the functionality to retrieve and review the documentation of a shared patient from another physician or clinician at a different organization, just as the functionality

that exists for physicians and clinicians within a single health care organization. It is not reasonable or practical to expect the physician or clinician to copy and move care summaries as an alternative solution; such an approach inhibits the physician or clinician from asking and/or answering specific questions and contributes to significant note bloat and information overload at the point of care. Additionally, the proposed exchange modalities focus on copying and distributing data to multiple locations and ignores the fact that, once data leaves the authoritative source, uncertainty exists around the reliability of the data copies. Clinicians should not make care decisions based upon potentially inaccurate, locally stored copies of data. **Both clinicians and patients need functions that facilitate finding and digging out the key pieces of clinical data that answer specific questions, and ONC should develop initial use cases that focus on that specific functionality. Even more valuable than the ability to send all available data classes is the ability to send a single data class in context that meets a clinical need.** Also, in many circumstances the ability to save a link to the authoritative source of the data may be more valuable than the ability to store a local copy.

Recognized Coordinating Entity

As previously mentioned, ONC intends to utilize a neutral, transparent, trusted and not-for-profit industry organization to serve as the RCE. While ONC will maintain the TEF itself, the RCE will be employed with developing, updating, implementing, and maintaining the CA – including the QTF. The RCE will also establish listening sessions and other mechanisms to gather and incorporate industry feedback in the development process of the CA. However, ONC will have the final say in approving the CA and future updated iterations. The College agrees there must be an underlying structure that both legally and technically connects the goals, objectives, and guiding principles of TEF and the technical details and rules regarding EHI exchange within the CA/QTF and supports ONC's proposal to contract a public-private entity to fulfil that need. It is crucial that in this role, the RCE serve as a facilitator, coordinator, and convener for all stakeholders and that they work collaboratively and fairly in identifying issues, alternatives, and solutions. **Clinicians, and medical specialty societies like ACP, need to be active participants in this work moving forward as they have not typically been included in these types of discussions in the past. Moreover, ACP recommends ONC include a tenet within "Appendix 2 Principle: Transparency" that RCEs should provide a process for receiving feedback from QHINs and implement them in a transparent manner.**

Timelines

ONC has extended the timelines for QHINs to implement updated technical standards from 12 months in the first draft to 18 months in the second draft. ACP believes that ONC acted appropriately in recognizing that the 12-month timeline was not reasonable to safely and reliably add functions and data elements. **However, the College reiterates our recommendations on Draft 1 of TEFCA that at least six months of the allotted 18-month implementation timeline be allocated for time after vendor implementation to allow physicians and other clinicians to implement them in their EHR systems and processes.** Additionally, as ONC and the RCE continue to update TEFCA, particularly the technical requirements contained with the QTF, ACP urges ONC to align these implementation timelines

with other technology upgrades needed to meet regulatory requirements in order to reduce clinician burden. For example, these upgrades should align the with Certification Program development and implementation timelines – so that clinicians are able to consolidate the time in which they are purchasing, implementing, and testing new functionalities within their systems.

Requests for Comments in the QTF

The QTF Draft 1 includes requests for comment to highlight where the industry can leverage the QTF development process to recommend appropriate standards or suggest alternatives to commonly used technology. ACP appreciates the opportunity to provide input and respond to the following requested items:

> *4. The Query function above describes a general workflow and set of capabilities for QHINs conducting query-based, inter-network document exchange. However, implementations may vary and result in divergence from the basic workflow. For example, a QHIN might fail to definitively resolve patient identity and consequently rely on a participant or Participant Member to determine the correct match. Likewise, Carequality's Query-Based Document Exchange Implementation Guide describes a number of alternate flows based on a "nominal flow." To inform subsequent work with the RCE to develop more specific technical guidance to address variation, comments are requested on the basic function presented and potential variations to consider.*

ACP Comments: As the RCE works to develop specific technical guidance around the query functionality, they may want to consider whether the best response to a particular query might contain only the accurate digital contact information for the treating clinician.

> *6. The IHE XCA profile is content-agnostic; it enables queries for documents based on metadata about the document but not the contents of the document itself. Therefore, the XCA profile does not necessarily support more granular queries for discrete data (e.g., a request for all clinical documents about a patient that contain a specific medication or laboratory result). Comments are requested on other appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR.*

ACP Comments*:* As we note in our discussion around the key use cases for EHI exchange, clinicians want to retrieve discrete answers to discrete queries. Rather than try to add this functionality to existing standards, it may be better to make this FHIR-based from the beginning, even if that delays its availability.

> *8. There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. For example, a centralized index of patient identity information may be more efficient for resolving patient identities across disparate communities, but also poses a greater risk to privacy if the system is compromised. Federated approaches may be less susceptible to external threats like cyberattacks, but harder to scale across many*

communities. Recognizing that new technologies and business entities with robust identity matching solutions may disrupt traditional approaches, should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs?

ACP Comments: Clinicians need flexibility in approaches to patient identity resolution and there needs to be constant evaluation of the usefulness of identity resolution approaches until the industry is able to develop a solution.

9. Different communities tolerate different degrees of risk with respect to accurately matching patient identities. Should QHINs meet a minimum performance standard (e.g., a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the algorithm(s) they rely on (e.g., by calculating precision, recall, etc.)?

ACP Comments: Clinicians need flexibility in approaches to patient identity resolution and there needs to be constant evaluation of the usefulness of identity resolution approaches until the industry is able to develop a solution.

10. Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs?

ACP Comments: It is probably too early to specify a single approach to record location services. ACP recommends the RCE, through their role as a public-private facilitator, coordinator, and convener of all relevant stakeholders, gather those that are doing record location services to learn what common approaches to record location might be. Record location services might also be a good substrate for discussion at the Health Information Technology Advisory Committee (HITAC).

Conclusion

Thank you for considering our comments on this extremely important technical framework and set of policies and procedures. Please contact Brooke Rockwern, MPH, Associate, Health IT Policy at brockwern@acponline.org if you have any questions or need additional information.

Sincerely,

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Chair, Medical Informatics Committee
American College of Physicians