February 20, 2018

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

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

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) Draft Trusted Exchange Framework and Common Agreement (TEFCA). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 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 appreciates ONC's work in developing the proposed policies, procedures, and technical standards outlined in the draft TEFCA and we agree with the underlying goals to achieve secure, seamless, and sustainable health information exchange to support the entire care continuum. The goals are based on well-established principles that should apply to all stakeholders: a single minimum set of rules from which to operate, building on existing initiatives, and focusing on private sector consensus standards and a private sector Recognized Coordinating Entity (RCE). The College's comments and priority recommendations on the draft TEFCA are discussed below.

Key Use Cases
The initial use cases proposed by ONC focus on the location and movement of large quantities of clinical data from place to place. These functionalities may be useful for some stakeholders, but these are not the use cases that will address the issues clinicians face with sharing and obtaining electronic health information (EHI). Clinicians need immediate answers to specific

questions at the point of care with minimal effort and time. There exists a large body of literature showing that clinicians generate multiple questions during an encounter, and if they cannot find answers quickly and easily, they tend to leave the question unanswered. None of the proposed use cases addresses this need.

The functionality that allows clinicians within a single healthcare organization to easily look up and review each other's documentation regarding a shared patient needs to be available to clinicians who are not in the same organization. Copying and moving care summaries is hardly a reasonable approach to permit the asking and answering of specific questions – and contributes to significant note bloat and an abundance of unnecessary information at the point of care. In addition, the focus of these proposed use cases on copying data and distributing them to multiple locations ignores the fact that, once disconnected from the authoritative source, the reliability of the copies becomes suspect. Clinicians should not make care decisions based upon locally stored copies of data because they may not always be accurate and safe.

ACP Recommendation: The initial focus of TEFCA should be on whatever will improve patient care. Both clinicians and patients need functions that facilitate finding and digging out the key nuggets 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, the ability to save a link to the authoritative source of the data may be more valuable in many circumstances than the ability to store a local copy.

Recognized Coordinating Entity
Regarding the proposal for a Recognized Coordinating Entity (RCE), ACP agrees that there needs to be a technical and legal coordinating process between the goals, objectives, and guiding principles of TEFCA Part A and the technical details and rules regarding EHI exchange. The College feels it is reasonable and appropriate to assign this function to a public-private entity working under contract to the Department of Health and Human Service (HHS).

ACP Recommendation: It is critically important that the RCE's primary function is to be a facilitator, coordinator, and convener, and to work transparently with all stakeholders to identify issues, alternatives, and solutions.

Implementation Details Contained in Part B
The Common Agreement should consist solely of principles that are enduring – not specific technical terms that will change throughout the lifespan of the agreements. Discussion of specific standards and processes should be removed from Part B entirely and the development of specific requirements should be assigned to the RCE who will facilitate transparent collaboration among relevant stakeholders in order to arrive at a starter set of specific use cases and implementation details. Moreover, the proposed implementation schedules of these new initiatives, including the schedule for updates, are overly ambitious. Our history with the Health Information Technology for Economic and Clinical Health (HITECH) program has clearly demonstrated that even simple changes can take multiple years to spread through the system. This program is far more ambitious than the HITECH program.

ACP Recommendation: **The development of standards and requirements should be assigned to the RCE who will facilitate transparent collaboration among all relevant stakeholders in order to arrive at a starter set of specific use cases and implementation details. Before any standard can be implemented, there must be a clearly defined detailed use case and a matching implementation guide (IG) that limits the implementation options for the specified use case.** For each standard proposed, there must be a use case, implementation guide, conformance testing tools, and successful pilot implementations available before an implementation timeline can be proposed. The RCE could work with the standards development organizations (SDOs) to develop the needed IGs. ONC's proposed 12-month timeline is too short to safely and reliably add functions and data elements. **Additionally, we recommend that at least 18 months be allowed between completion of pilot testing of an implementation guide and expectation of support throughout the network. In particular, at least six months should be allocated for time after vendor implementation to allow physicians and other clinicians to implement them in their EHR systems and processes.**

Single On-Ramp
One key objective proposed by ONC is the notion of a single on-ramp for all users and uses of the network. This concept of a single on-ramp would attempt to hide the complexity and variation involved in different uses behind a common interface.

ACP Recommendation: Attempts to minimize cost and complexity for users 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. The College completely agrees with a goal to minimize the number of connections a provider would have to implement and use. However, we have concerns that ONC's proposal for a "single on-ramp" to EHI is not 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 various applications necessary for true interoperability (e.g., Health Information Networks (HINs), Direct, e-Prescribing, Quality Report, Public Health Reporting, billing operations, etc.) For example, e-prescribing is a complex transaction system that would not work as well if it had to use a general-purpose portal.

Thank you for considering ACP's comments. Please contact Brian Outland, PhD, Director, Regulatory Affairs, by phone at 202-261-4544 or e-mail at boutland@acponline.org if you have questions or need additional information.

Sincerely,

Patricia L. Hale, MD, PhD, FACP
Chair, Medical Informatics Committee
American College of Physicians