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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

February 20, 2018

Via Email

Genevieve Morris,

Principal Deputy National Coordinator for Health Information Technology,
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services (HHS)

RE: Draft Trusted Exchange Framework and Common Agreement

Dear Ms. Morris:

The American College of Cardiology (ACC) is pleased to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on its Trusted Exchange Framework and Common Agreement (TEFCA). Section 4003 (b) of the 21st Century Cures Act stated the “the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks.” After holding several meetings and soliciting stakeholder feedback, ONC released the draft TEFCA on January 5, 2018. The TEFCA is designed to serve as a voluntary single “on-ramp” to interoperability by building on existing industry work. The draft TEFCA provides principles for the framework and defines minimum required terms and conditions for participation in the agreement.

The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards, and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the Journal of the American College of Cardiology (JACC), ranked number one among cardiovascular journals worldwide for its scientific impact.

Interoperability Importance

The College believes complete interoperability of health information technology (HIT) is essential to efficient and high-quality care for patients and is of the utmost importance to the ACC’s diverse membership of cardiovascular care team

members including physicians, physician assistants, nurse practitioners, nurses, and practice administrators. Interoperability will also enhance the ability of clinical data registries to measure and improve the quality of care for patients. Clinical data registries such as the National Cardiovascular Data Registry (NCDR) assist clinicians, hospitals, and government agencies in monitoring and continuously enhancing the quality of care.

Interoperability requires more than the ability of two or more health information systems or components to exchange clinical and other information; it also requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes. While there are currently standards that Electronic Health Records (EHRs) must meet, common data standards must exist to fix challenges clinicians continually face when exchanging the simplest elements of data between EHRs.

Recognizing Interoperability Investments

The College appreciates ONC's efforts to not only acknowledge the efforts taken by organizations to address interoperability issues and work towards common data standards, but to also recognize that additional work is necessary to correct usability problems and other issues that prevent the realization of true interoperability. The College believes that the TEFCA is a step in the right direction. Developing a voluntary framework designed to provide stakeholders with the necessary principles, as well as the terms and conditions, to support interoperability is superior to mandating participation in a prescriptive system that could prevent necessary innovation and progress.

However, for the TEFCA to successfully contribute to continued progress, it is essential that ONC and the Recognized Coordinating Entity (RCE) charged with enforcing the terms and conditions of the Agreement recognize the substantial investments that stakeholders have already made into existing data systems such as EHRs, registries and qualified clinical data registries (QCDRs). Adapting existing networks to meet future standards and updating existing user agreements could impose substantial financial and administrative burdens on stakeholders. As ONC chooses the RCE and develops the final TEFCA, ONC should consider the following comments regarding the TEFCA, including the principles for trusted exchange and minimum required terms and conditions for the trusted exchange.

Trusted Exchange Framework Overview

According to ONC, the TEFCA is designed to serve as a "minimum set of policies, procedures, and technical standards are intended to advance interoperability...and enable [stakeholders] to use health information networks (HINs) to support the many use cases that are important to them and their patients (clients)..." As previously stated, the College acknowledges and appreciates this voluntary approach by ONC; however, the TEFCA, as currently drafted, insufficiently defines the terms to which organizations are expected to adhere. Additionally, the draft TEFCA fails to provide enough clarity for organizations to know whether ONC would consider them a HIN. While the College understands the ONC and RCE will develop additional terminology and furnish clarification in the future, the College strongly encourages both ONC and the RCE to more clearly define TEFCA

terminology now. Additionally, the College recommends that ONC and the RCE provide sufficiently clear explanations through use cases and examples, so organizations can easily understand how TEFCA will affect them. It is important that any use cases, agreed-to principles and other decisions made by ONC and the RCE in the future are scientifically sound and do not provide undue influence for commercial gain for certain organizations. Furthermore, the College encourages ONC to take a transparent approach to the development of these principles, use cases, and additional provisions by allowing public inspection and sufficient time to provide comments. Finally, because the RCE will be tasked with operationalizing the TEFCA, it is important for ONC and the RCE to clearly define “non-conformity” for enforcement purposes. For example, would malicious intent be required for the RCE to act against a Qualified Health Information Network (QHIN) for not conforming to the TEFCA, or would the inability of the QHIN to meet certain TEFCA requirements suffice for legal action?

Considering Administrative Burdens Place by TEFCA

Consideration of the potential financial and administrative burdens placed on QHINs and HINs is also important. ONC acknowledges the TEFCA may necessitate modifications to existing participation agreements and trust frameworks to support provisions, but the Agency believes these changes are necessary to meet objectives outline by Congress and “will enable providers and patients to have a single “on-ramp” to exchange.” While the College is sympathetic to and appreciates the balance ONC must strike to work to achieve true interoperability, ONC must consider that significant costs may be required to achieve this goal and the impact this could have on participation in TEFCA.

While certain modifications to existing participation agreements could be made quickly and distributed to all users through electronic means, more extensive modifications could become very labor intensive and expensive. The execution of modified agreements could require additional negotiations between legal offices of participating sites, adding to the administrative and financial burden. Should the ONC and RCE impose standards that are expensive and onerous for potential HINs and QHINs to adhere to, these organizations will simply not participate rather than incurring undue and unnecessary costs. In the past, standards have been developed and adopted without assurances that all parties agree on implementation. Instead, organizations would develop their own implementation guides, essentially defeating the purpose of coalescing around a single standard. The College encourages ONC and the RCE to balance the statutory requirements with the burdens imposed on participants, ensuring the highest possible participation rates.

Part A- Principles for Trusted Exchange

The following comments relate to specific principles outline in Part A of the TEFCA.

Principle 1) Standardization: Adhere to industry and federally recognized technical standards, policies, best practices, and procedures

Currently, NCDR closely adheres to Consolidated-Clinical Document. Architecture (C-CDA) standards, but it does not meet all the required criteria. While the College understands the desire to have all participating organizations to adhere to the same standards for interoperability purposes, it is important that the RCE and the RCE recognize organizations have made a good faith effort to adhere to all other federally required standards (such as those required for clinical data registries). As such, TECFA should align with federally required standards or provide sufficient time to allow organizations to adhere to additional standards at their own pace. Additionally, it is essential that the RCE and the RCE provide relative stability for standards. Organizations that do modify their standards to adhere to TECFA requirements will expend considerable resources to do so and should be rewarded with stability to ensure a sufficient return on their investments.

Principle 2) Transparency: Conduct all exchange openly and transparently

When developing principles involving transparency, it is vital that the RCE and the RCE take into consideration the wide variety of HINs and QHINs that could participate under the Agreement. While the College strongly supports the development of principles encouraging transparency, flexibility to account for a diverse ecosystem of HINs and QHINs is important. It is also important for the RCE and the RCE to sufficiently define “public availability” with respect to terms and conditions. For example, any individual can receive the terms and conditions for participation in NCDR, but they must provide contact information to NCDR to do so. The College seeks clarification on specific terms necessary to meet public availability criteria to ensure all potential participants clearly understand the agreement’s requirements.

Principle 4) Privacy, Security, and Safety: Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity

The College seeks clarification from the RCE as to how limited data sets under the Health Insurance Portability and Accountability Act (HIPAA) and de-identified data sets would be viewed for the purposes of this draft agreement. As drafted, TECFA does not provide sufficient clarity on how limited and de-identified data sets would fit into the Agreement. Currently NCDR has developed a core data set, but it is not aligned with existing standards. The College is working toward standard nomenclature alignment, where possible, but this effort takes considerable time and resources.

Principle 5) Access: Ensure that Individuals and their authorized caregivers have easy access to their Electronic Health Information

The College has long supported ensuring patients have the ability to access and control their electronic health information safely and efficiently. Including this in the goals of the TECFA to ensure individuals and their caregivers have this access is laudable, and the College looks forward to working with the RCE to ensure the realization of this goal. However, the College does have concerns with requirements that participants maintain policies and procedures allowing a patient to revoke his/her participation in the QHIN on a prospective basis. As previously mentioned, TECFA will impact a diverse ecosystem of stakeholders including clinical data registries **such as** NCDR, and the requirements must be flexible to accommodate this diversity.

HIPAA Health Operations

The NCDR operates under the premise that the “Health Care Operations” component of HIPAA Privacy Rule allows for the performance of quality assessment and improvement activities with explicit patient consent. Currently, data are reported retrospectively on all patients seen by participants for specific clinical data registries. Data from medical records, which by law are already accessible to patients, are aggregated, providing participants with the ability to benchmark their performance with similar organizations across the country to improve the quality of patient care. To ensure accurate representations of performance, it is critical that data on all relevant patients be included in the registry. Additionally, the College has gone to great lengths to ensure that any registry activities outside of the definition of health care operations meet the relevant HIPAA requirements for privacy and security. The ACC believes that HIPAA is sufficient for covered entities, and TEFCA requirements should not extend beyond HIPAA for participants such as clinical data registries which already have sufficient protections in place.

National Coverage Decision Requirements

In addition to potentially impeding quality data collection activities, allowing patients to opt-out of registry participation could affect the ability of clinicians to be paid for their services. The STS/ACC TVT Registry™, created by a collaboration between The Society for Thoracic Surgeons (STS) and the ACC, monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures. The TVT Registry is approved by the Centers for Medicare & Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage decisions (NCD) for transcatheter aortic valve replacement and transcatheter mitral valve repair. Likewise, the LAO Registry™, which captures data on left atrial appendage occlusion (LAO) procedures to assess real-world procedural outcomes, short and long-term safety, comparative effectiveness and cost effectiveness, is approved by CMS to meet the registry requirements outlined in the national coverage decisions for Percutaneous Left Atrial Appendage Closure. Collecting data through the TVT and LAO Registry is required for physicians to receive payment for these lifesaving therapies. The College understands and supports the Agency’s desire to empower patients by ensuring they have access to their health information; however, allowing them to opt out of registry participation could affect the ability of physicians to be paid for their services. To ensure a wide breadth of organizations can participate, the ONC and RCE must take into consideration the wide variety of potential HINs and QHINs and their differing purposes that will participate under the agreement and whether patients have access to this data through other means, such as directly from their clinicians.

Increased Administrative Burden

NCDR participants are hospitals or clinicians, rather than patients. Given the lack of relationship between the ACC or NCDR and patients, the College is concerned that ONC would be imposing a substantial administrative burden on entities that do not have a direct relationship with patients by requiring the maintenance of policies and procedures allowing a patient to revoke his/her participation, in addition to generating unnecessary and potentially harmful concerns among

patients. If ONC were to finalize this principle, it would necessitate the development of new systems and processes to track consent from patients, adding to the administrative burden placed on entities such as clinical data registries.

Part B- Minimum Required Terms and Conditions for Trusted Exchange

Part B- Minimum Required Terms and Conditions for Trusted Exchange builds upon definitions set out under HIPAA, and together with Part A- Principles for Trusted Exchange, is designed to help allow for seamless electronic health information exchange and increased interoperability. The College supports this aim and encourages ONC and the RCE to continue to work with stakeholders beyond development of the final TEFCA, as unforeseen burdens and technological innovations necessitate modifications. While some of these definitions, terms and conditions are defined in statute, the College encourages both ONC and the RCE to remain flexible and make necessary adjustments to maximize organizations' ability to participate in the agreement. Regarding the terms for trusted exchange for which ONC has proposed definitions, the College has some comments:

- **Attributable Cost-** The College reminds ONC and the RCE that it is important that ONC and the RCE ensure that “reasonable allowed costs” do not prohibit participation in TEFCA. As previously mentioned, HINs and QHINs will not all be equal, with varying resources, services, and infrastructure. Reasonable costs could widely differ for smaller organizations as compared to those of large health networks, both of which could choose to apply for QHIN status. ONC and the RCE should make a concerted effort to further define reasonable allowed costs, allowing flexibility for the variability in HIN and QHIN size and resources.
- **Health Information Network-** In addition to the development of use cases and examples to allow organizations to understand the scope of TEFCA, the College requests further clarification on the definition of “two or more unaffiliated individuals or entities.” By sufficiently defining affiliated individuals or entities, ONC can provide clarification as to whether clinical data registries would be considered HINs under TEFCA.
- **Minimum Core Objectives-** Minimum Core Objective is used in the User Guide as a requirement for QHINs. However, Minimum Core Objective is not defined in Part B under the QHIN definition or as a separate term. ONC should sufficiently define ALL requirements for HINs and QHIN, so potential participants have a complete understanding of requirements.

Conclusion

The ACC thanks ONC for allowing it to provide comments on the draft TEFCA and looks forward to continuing to work with ONC, the RCE and other regulatory agencies to address issues surrounding interoperability. To address these comments or if you have additional questions, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at jcody@acc.org.

Thank you,

Mary Norine Walsh

Mary Norine Walsh, MD, FACC
President