

The American Medical Association (AMA) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) proposed draft of the Trusted Exchange Framework and Common Agreement (TEFCA, Common Agreement, or Framework). Overall, the AMA supports ONC's goals for the TEFCA, including the ability to (1) provide physicians access to health information about their patients, regardless of where the patient received care; (2) provide patients and their caregivers to access their health information electronically without any special effort; and (3) ensure that organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals. We also appreciate ONC's desire to create a single "on-ramp" for physicians and patients and recognize the overarching need to simplify and clarify the process and governance required for nationwide health information exchange (HIE).

While the draft TEFCA lays out the principles, terms, and conditions for trusted exchange, there are a number of critical questions and concerns that ONC must address prior to releasing a final draft. We also highlight that the scope and pace of the draft initiatives are very ambitious, and it is not clear if the proposed TEFCA process will ultimately achieve ONC's goals. Through that lens, the AMA is providing specific feedback and suggestions, and requests that ONC provide further information on the questions included in these comments.

Principles to achieve health care goals

The AMA provided comments to ONC during its first public comment period on the TEFCA. Our comments highlighted the importance of recognizing ongoing efforts by private sector stakeholders, and we appreciate ONC's efforts in the draft TEFCA to survey the HIE landscape and identify areas where greater harmony could lower exchange cost, complexity, confusion, or other friction points.

We also recommended that ONC consider realistic and achievable goals for the TEFCA, that the agency derive these goals from provisions within the 21st Century Cures Act (Cures), and use the goals as a metric for measuring success. Furthermore, we recommended avoiding duplication of existing agreements and additional complexity and burden on physicians. Our major goals for a successful Framework include the following:

- The Framework should address, at a national level, the business, technical, and governance components of interoperability to achieve patient-centered care;
- The Framework should incorporate Cures provisions around vendor information blocking and access to longitudinal patient health records while also limiting administrative burden; and
- The Framework should empower physicians and patients with clear and up-to-date information about the value proposition, structure, and limitations of health information exchange networks.

Health information exchange principles—technical

With respect to the first goal, ONC has acknowledged the importance of technical standards in interoperability.

TEFCA language:

The 2015 Edition certification criteria (2015 Edition) help facilitate greater interoperability for several purposes and enables Electronic Health Information exchange through new and enhanced certification criteria, standards, implementation specifications, and Certification Program policies.

Certification enables End Users to have confidence that their health IT will support interoperability for the appropriate use cases and helps enable the exchange of Electronic Health Information in a structured way.

If the Certification Program or the ISA [Interoperability Standards Advisory] do not have applicable standards, Qualified HINs [Health Information Networks] should then consider voluntary consensus or industry standards that are readily available to all stakeholders, thereby supporting robust and widespread adoption.

At a minimum, Qualified HINs connecting to other Qualified HINs should adopt and use standards and implementation specifications that are referenced in the 2015 Edition final rule and the ISA. Further, Qualified HINs should actively engage with ONC to improve and update the ISA's detail, in order to inform the content of the ISA and ensure that the appropriate and best standards are referenced for needed use cases.

Finally, Qualified HINs and their participants should work collaboratively with standards development organizations (SDOs), health systems, and providers to ensure that standards, such as the C-CDA, are implemented in such a way that when Electronic Health Information is exchanged it can be received and accurately rendered by the receiving healthcare organization.

The AMA appreciates ONC's attempt to leverage the uniformity health IT certification brings to the industry, and agrees with ONC that, beyond 2015 Edition, the ISA is the next logical collection of standards to assist with meeting interoperability needs. However, while we recognize the need to anchor technical methods of interoperability to a common set of requirements, AMA seeks clarification as to how ONC intends to ensure conformance to these standards and how certification criteria or ISA standards are the right fit for interoperability at this scale.

TEFCA language:

Qualified HINs should ensure that the data exchanged within their own network and with other Qualified HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. Qualified HINs may consider using open source tools, such as ONC's C-CDA scorecard tool for testing the quality of C-CDAs. They may also consider developing tools to test the quality of data exchange using Fast Healthcare Interoperability Resources (FHIR) APIs. These types of testing programs can help ensure that high quality data is exchanged both within and across HINs.

The AMA agrees that Qualified HINs (QHINs) should ensure Participants (that is, persons or entities participating in QHINs) conform their own networks to the appropriate minimum quality standards' implementation guides, and that testing tools are available to support this need. However, while the draft TEFCA identifies 2015 Edition as the bases for interoperability, ONC has downplayed the utility of robust, continuous, and transparent testing to achieving national interoperability.

The AMA has regularly highlighted the importance of health IT testing and has urged ONC to focus its efforts on the validation of system interoperability, usability, and safety. Since 2015 Edition criteria will play a major role in underpinning interoperability in the TEFCA, the Framework's draft language leads to the assumption that products certified by the 2015 Edition process will have already performed the testing necessary to ensure system-to-system interoperability. There seems to be a further assumption that this level of testing will be sufficient to ensure the complex interactions between disparate health IT products, HIEs, QHINs, Participants, and End Users (that is, individuals or organizations using the services of a Participant to send and/or receive electronic health information), and the ability of these technologies to consistently and seamlessly facilitate the permitted purposes, goals, and use cases identified in the draft TEFCA. **We do not believe this to be the case and are concerned with these assumptions.** In addition, the importance of testing is only briefly mentioned near the beginning of the draft TEFCA, while the concept of "burdensome testing" is mentioned at least four times. The AMA questions as to why ONC positioned testing in a negative connotation instead of addressing the pros and cons of testing principles.

ONC has made efforts to improve conformance testing in its certification program, and has extended its oversight of health IT to in-the-field product surveillance. While we acknowledge that ONC has made some attempts to address our concerns, ONC's certification program, and therefore 2015 Edition, is tooled for compliance to Centers for Medicare & Medicaid Services (CMS) programmatic requirements. Clearly, testing an electronic health record (EHR) for Meaningful Use (MU) or Advancing Care Information (ACI) programs is not the same as validating a system's ability to empower individuals to use their electronic health information to the fullest extent; enable providers and communities to deliver smarter, safer, and more efficient care; and promote innovation at all levels—all of which are explicitly listed in the draft TEFCA as components of an interoperable health system.

The AMA strongly urges ONC to clarify and identify the discrepancies between 2015 Edition and the gaps that must be bridged to align health IT development, design, and testing with ONC's stated TEFCA goals.

Again, the AMA supports a nationwide trusted exchange framework; however, we are concerned with the assumptions outlined above as they relate to standards use and conformance testing. As stated earlier, ONC has extended its oversight into certified health IT, particularly those products used in production environments. Would ONC then leverage its in-the-field surveillance capability if concerns were raised about the conformance of health IT's certified criteria as it relates to TEFCA? **The AMA seeks clarity from ONC on where it believes its oversight role intersects with a QHIN's oversight and/or that of a Recognized Coordinating Entity (RCE).**

TEFCA language:

A. Adhere to standards for Electronic Health Information and interoperability that have been adopted by the Secretary of the U.S. Department of Health & Human Services (HHS) or identified by ONC in the Interoperability Standards Advisory (ISA).

The AMA believes the description of this principle discourages the use of standards with patented technologies or other intellectual property. We disagree with this as an overarching concept and recommend that any standards need to be considered for inclusion if they are embedded and widely used in current health care exchanges, as replacing them would cause a larger burden on the health care system.

Health information exchange principles—governance

ONC has proposed a multi-layered approach to governance. This approach suggests a hierarchical structure, positioning a single entity—the RCE—to manage the oversight and day-to-day operations of the TEFCA. Additionally, ONC states the RCE will be charged with onboarding organizations to the final TEFCA; ensuring QHINs comply with the terms and conditions of the TEFCA; addressing non-conformities with QHINs; developing additional use cases; updating the TEFCA over time; and working collaboratively with stakeholders.

The AMA recognizes the need for an RCE and supports ONC's proposed approach.

TEFCA language:

To operationalize the Trusted Exchange Framework, the RCE will incorporate additional, necessary provisions into the Common Agreement as long as such provisions do not conflict with the Trusted Exchange Framework, as approved by ONC. The RCE will be expected to monitor Qualified HINs compliance with the Common Agreement and take actions to address any non-conformity with the Common Agreement—including the removal of a Qualified HIN from the Common Agreement and subsequent reporting of its removal to ONC. The RCE will also be expected to work collaboratively with stakeholders from across the industry to build and implement new use cases that can use the TEFCA as their foundation, and appropriately update the TEFCA over time to account for new technologies, policies, and use cases.

ONC believes that a private-sector organization would be best positioned to serve as the RCE and, to that end, we intend to release an open and competitive Funding Opportunity Announcement (FOA) in spring 2018 to award a single, multi-year Cooperative Agreement to an RCE. The multi-year Cooperative Agreement will allow ONC to closely collaborate with the RCE to help ensure that the final TEFCA supports all stakeholders and that interoperability continues to advance. In general, we believe the RCE will need to have experience with building multi-stakeholder collaborations and implementing governance principles. The FOA announcement will provide additional specificity on the eligibility criteria that an applicant would have to meet to be chosen as the RCE.

The AMA looks forward to further clarification from the ONC on what the RCE is and what its unique role will be in the health care interoperability ecosystem. Based on the description above, and other language in the draft TEFCA, we believe ONC envisions the RCE playing a number of different roles, including convener; arbitrator; contracts administrator; trainer; enforcer; overseer; and the standards developing organization (SDO)/technical compliance entity.

The development of additional use cases is a major factor in the success of the TEFCA, and therefore, use case development must be a priority for the RCE. While a broadcast query for treatment purposes is an important aspect of nationwide interoperability, we also foresee the need to replicate high-impact use cases. For instance, many new Alternative Payment Models (APM) utilize a combination of Certified EHR Technology (CEHRT) and custom-developed software to engage patients or manage populations. Results have decreased hospitalizations and emergency room visits, reduced spending, and improved patient satisfaction.¹ Still, it is extremely difficult for health care providers to receive timely and actionable data from payers. Replicating these results across the nation will require exposing health IT developers to successful APM health IT frameworks. **To that end, we recommend that the RCE also act as a “use case clearinghouse” to help ensure that health IT developers, QHINs, and Participants accommodate the needs of new care models.**

Representing and accommodating the needs of the End Users should be a major factor in the governance of the RCE. **The AMA recommends that the RCE be overseen by a regularly-meeting governing board that includes representation from the provider community, patient/non-covered entity community, and public health community. The AMA emphasizes that the RCE should have independence from ONC with transparent accountability and governance.**

Information blocking

Information blocking constitutes activities that prevent, interfere with, or discourage electronic transmission and sharing of electronic health information across the medical community. The AMA has long prioritized the reduction of vendor-driven information blocking, and to this end, we suggested that the TEFCA establish a “floor” for limiting information blocking. Unfortunately, while CMS has implemented requirements around provider information blocking, ONC has yet to operationalize Cures information blocking requirements for health IT vendors.

With the release of the draft TEFCA, we are perplexed as to why ONC has decided to seek feedback on a national interoperability framework without first promulgating a notice of proposed rulemaking on vendor information blocking. **Guidance relating to what does and does not constitute information blocking is a critical component missing from the draft TEFCA.** While the draft Framework contemplates actions that may limit access to electronic health information, not enough information is available to sufficiently inform comments in this area. **The AMA strongly urges ONC to reopen a public comment period on the draft TEFCA once information blocking regulations are in place.**

¹Illinois Gastroenterology Group. Proposal to the Physician Focused Payment Model Technical Advisory Committee (PTAC) on *Project Sonar*. <https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf>

The AMA also seeks clarity as to ONC's intent on leveraging the TEFCA as a component in information blocking considerations. For instance, would participation in the TEFCA constitute not preventing, interfering with, or discouraging electronic transmission and sharing of patient health information? What roles will QHINs or the RCE play in determining failure to abide by the terms and conditions of the Common Agreement as it relates to information blocking? If an entity reports a failure by another Participant or End User to incorporate or to abide by the terms and conditions of the Common Agreement, how would an appeals process be managed?

TEFCA transparency and physician burden

TEFCA language:

All parties desiring to participate in Electronic Health Information exchange should know, prior to engaging with a Qualified HIN, the responsibilities of being a participant in a Qualified HIN, the responsibilities of acting as a Qualified HIN, and the protections that have been put in place to ensure that all privacy and security requirements are followed. Qualified HINs should voluntarily make these and other terms and conditions for participating in their network easily and publicly available via their website; meaning they are not accessible only to members but also to the general public.

The AMA applauds the draft TEFCA's principles promoting transparency and cooperation/non-discrimination. However, we encourage ONC to more explicitly address issues of stakeholder choice and voluntary participation in QHINs in the final TEFCA principles. Due to the sensitive nature of electronic health information and the potential disruption to physician practices involved in implementing the required technology, **the AMA underscores the importance of ensuring that Participants understand and can willingly elect to participate in information sharing via QHINs.** Some of the potential users and use cases outlined in the draft TEFCA raise questions as to physicians' ability to willingly participate (or not participate) in QHINs. Specifically, in many states and cities, physicians' financial viability is entirely dependent on participation in particular health insurer networks.

For example, 43 percent of US metropolitan areas have a single health insurer with at least half of the commercial insurance market share. In locations such as these, physicians would face potentially insurmountable financial disadvantages if they were to choose not to participate in the dominant insurer's network. In turn, this would force physicians to agree to the dominant insurer's terms of participation for a QHIN that they might otherwise oppose, including participation in a QHIN about which they have technological or security concerns. Physicians could also be forced to join multiple QHINs based on different health plans' requirements for network providers, which could impose significant financial burdens upon practices—particularly smaller practices with already strained resources. **As a result, we recommend that ONC add language to the TEFCA that protects physicians' ability to voluntarily join a QHIN and prevents insurers from requiring QHIN participation as a term of network contracts.**

Improved accessibility to health information has the potential to transform care delivery and improve patient outcomes, particularly as the US health system transitions from a fee-for-service model to value-based payment. However, earlier efforts in improving data accessibility through HIEs have faced obstacles in funding and long-term stability and viability. As such, we urge ONC to analyze the challenges that have undermined and curtailed past efforts to improve the exchange of health information so that learnings from those endeavors can be applied to the TEFCA. **Specifically, we encourage ONC to audit current/operational and past/failed HIEs to identify key factors that have played a role in the success or failure of other data exchange initiatives. This evaluation should examine ways to ensure that funding and viability issues will not threaten the success of this new initiative to build QHINs.**

TEFCA value proposition, structure, and limitations

TEFCA language:

Payers and health plans, including employer sponsored group health plans may wish to work with Qualified HINs to connect to Electronic Health Information that would better support payment and operations, including using analytics for services such as assessing individuals' risk, population health analysis, and quality and cost analysis. These Population Level requests are fundamental to providing institutional accountability for healthcare systems across the country.

Supporting these types of use cases necessitates the ability to exchange multiple patient records at one time (i.e. population level or "bulk transfer"), rather than potentially performing hundreds of data pulls or pushes for a panel of patients. Qualified HINs should provide the ability for participants to both pull and push population level records in a single transaction. This decreases the amount of time a clinician's resources are devoted to such activity and makes more time available for actual patient care.

End Users should have access only to the information they need for a given purpose, consistent with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's minimum necessary standard. The AMA agrees that reducing the difficulties inherent in accessing medical information at the individual or population health level is an important goal; however, we have concerns with the potential pitfalls of stakeholders having unprecedented access to information across the health care system. Current data request processes, while limiting, are narrowly scoped for specific use cases and involve some level of "gating" that helps prevent improper use and disclosure, and helps enforce compliance on both ends of the transaction (collection (query) and disclosure). The TEFCA must ultimately include mechanisms to limit data exchange in response to both broadcast and directed queries to the minimum amount of information necessary.

We strongly recommend that ONC consider all ramifications of bulk data access, including privacy and security of an individual's electronic health information, and situations that may inadvertently result in "select all & copy". Clearly, increasing ease of access to data is an imperative; however, ONC must also consider the need to hold entities accountable, including assuring that covered entity End Users can comply with HIPAA's minimum necessary

obligations in both launching and responding to queries. **We recommend ONC explore mechanisms such as: 1) requiring QHINs to monitor query and response logs and take action against Participants and End Users who abuse the openness of the system through overly broad queries (for example, suspending or revoking query rights); and 2) establishing a mechanism—by way of a QHIN or RCE—for receiving and promptly resolving complaints about abuse of the system.**

The AMA appreciates that a Participant or End User's failure to comply *may* result in terminating access to data (as oppose to automatically resulting in termination). It may be beneficial to lay out remedial steps such as a corrective action plan prior to resulting in termination so that all parties have knowledge of the noncompliance and what steps need to be taken to remedy.

TEFCA language:

6.2.4 Identity Proofing. Each Qualified HIN's security policy shall include the following elements to ensure appropriate identity proofing: (i) End Users/Participants. Each Qualified HIN shall identity proof Participants and participating End Users at a minimum of IAL2 prior to issuance of credentials;

9.1.4 Identity Proofing. Each Participant shall identity proof participating End Users and individuals in accordance with the following requirements: (i) End Users. Each Participant shall identity proof participating End Users at Identity Assurance Level 2 (IAL2) prior to issuance of access credentials;

The AMA seeks clarification on the specific identify proofing process envisioned by ONC as the draft TEFCA describes two separate identify proofing processes. It is not clear if ONC intends for each QHIN to provide identify proofing services for its Participants and End Users, i.e., top down, or if QHINs will provide a one identity proofing service while Participants provide yet another, i.e., distributed and non-centralized. In discussing the draft TEFCA's approach with other stakeholders, the AMA has encountered different perceptions as to the actual process.

The AMA supports the ultimate goal of reducing the friction and cost associated with identify proofing. However, given the confusion around ONC's approach, the AMA requests further clarity. For instance, if a QHIN provides an identify proofing service for all of its Participants and End Users, how would this service be managed, distributed, and funded? Would all physician offices be required to implement new software and services for identify proofing patients? Furthermore, what educational process will be developed to ensure all individuals, End Users, and Participants are clear on the use and security of the identities? Overall, AMA is concerned about the additional burden of and potential cost to physicians participating in the TEFCA that are going to be required to identity proof individuals.

The AMA also notes that ONC has not addressed an important component of the Cures language as it relates to the TEFCA. Cures requires ONC to work with the National Institute for Standards and Technology (NIST) around interoperability pilot tests:

“(iii) PILOT TESTING.—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 established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.”

Given the complexities, interdependencies, costs, and potential burdens of establishing, managing, and deploying a nationwide identity proofing process, the AMA strongly urges ONC to pilot test, in consultation with NIST, any and all identity proofing methods considered for use in a national trusted exchange framework prior to finalizing the TEFCA. Considering the importance of managing access, authorization, and authentication at this scale, ONC would be remiss to not leverage appropriate pilot testing to bolster confidence and trust in the privacy and security of patient health information.

TEFCA language:

9.1.1 Permitted Purposes. Each Participant shall support all of the Permitted Purposes by providing all of the data classes the then current USCDI when and to the extent available when requested and permitted by Applicable Law. Each Participant shall respond to Queries/Pulls for the Permitted Purposes.

10.1 Each Participant shall be responsible for ensuring that the obligations described in this Section 10 shall be incorporated into all existing and future End User Agreements.

Some state and federal laws do require patient consent for exchange of Electronic Health Information. For example, for some health conditions such as HIV, mental health, or genetic testing, state laws generally impose a higher privacy standard (e.g., requiring patient consent from the individual) than HIPAA. Additionally, under 42 C.F.R. Part 2, subject to certain exceptions, federally assisted “Part 2 programs” are required to obtain consent to disclose or re-disclose health information related to substance use disorder information, such as treatment for addiction. When required by federal or state law, a Qualified HIN’s ability to appropriately and electronically capture a patients’ permission to exchange or use their Electronic Health Information will engender trust amongst other Qualified HINs seeking to exchange with that network.

The AMA seeks clarification as to the parties, purposes, and differences of the Common Agreement, Standard Agreement, Participant Agreement, and End User Agreement. Understanding these agreements and the relationships among them and their signing parties is critical due to the contractual enforceability mechanisms; unlike EHR certification and information blocking, ONC will have limited ability to oversee the TEFCA. Specifically, Section 10 of the draft Framework discusses an “End User Agreement” as a term of art; however, it is not a defined term in Section 1. Thus, it would be beneficial for ONC to describe this agreement and how it differs from a Participant Agreement.

In explaining the different types of agreements, clarification is needed with respect to each agreement is meant to act as a business associate agreement, how a business associate agreement interacts with the agreement, or if the business associate agreement is meant to be a separate agreement. For example, could a Participant enter into a business associate agreement with a QHIN that limits the permitted purposes for which the QHIN can use the data to treatment and public health or does Section 9.1.1 trump all existing business associate agreements that Participant may have with the QHIN?

Ethical Obligation of Confidentiality

The AMA is concerned about the breach of trust with patients and potential liability against physicians and other health care providers of unauthorized disclosure of a patient's information especially (1) if the sharing or pulling of information from a Participant is automatic without any human confirmation or interaction and (2) if Section 9.1.1 will trump any business associate agreement a Participant may have with a HIN or QHIN, which means the Participant must share any data that is requested and permitted under law.

Physicians take patient privacy and confidentiality seriously. In keeping with the professional responsibility to safeguard the confidentiality of patients' personal information, physicians have an ethical obligation to manage medical records appropriately.² Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.³ Thus, physicians may face severe sanctions and liabilities when they breach this trust, as well as the loss of their patients' confidence.

The AMA is concerned that a physician may be liable for unauthorized disclosures when the query/pull is automatic and outside the control of the physician or physician staff. In addition, we have concerns as to whether a physician would be found to be non-compliant with the Common Agreement when he or she reasonably withholds information because its release would damage the physician-patient relationship. ONC should consider whether it is appropriate to have indemnification of Participants or End Users in certain situations when the decision to disclose data is outside the control of the Participant or End User. Relatedly, the AMA also seeks clarification to Section 9.1.1 as to what safeguards will exist to ensure that the permitted purposes are "permitted by Applicable Law"?

Specifically, due to the lack of data segmentation capabilities of many EHRs, some physicians are unable to send data electronically at a granular level. In the event that a physician has sensitive data subject to a higher privacy standard (e.g., imposed by state law or by 42 CFR Part 2), physicians may be unable to send electronic health information while still complying with applicable law, even if the data requested is not subject to a higher privacy standard. **The**

² AMA, Medical Code of Ethics. <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-3.pdf>

³ Id.

TEFCA must specifically incorporate protections for those who cannot share queried data as a result of their EHR design, such that those physicians are not in violation of the Common Agreement.

TEFCA language:

9.2 Participant Compliance. Each Qualified HIN shall be responsible for taking reasonable steps to ensure that all Participants are abiding by the obligations stated in this Section. Each Qualified HIN further shall require that each Participant provide written documentation evidencing compliance with these obligations on at least an annual basis. In the event that a Qualified HIN becomes aware of a Participant's non-compliance with any of the obligations stated in this Section, then the Qualified HIN immediately shall notify the Participant in writing and such notice shall inform the Participant that its failure to correct any deficiencies may result in the Participant's removal from the Health Information Network.

Section 9.2 of the draft Common Agreement requires that Participants must provide written documentation evidencing compliance on at least an annual basis for each Qualified HIN. While the AMA appreciates the importance of demonstrating compliance, this requirement will add more administrative burden upon physicians that will add unnecessary costs to the health care system. Reducing administrative burden is an important goal to the AMA because it diverts time and focus away from patient care and leads to additional stress and burnout among physicians. **At the very least, ONC should create a standardized compliance form for Participants rather than potentially having Participants fill out multiple forms from each QHIN they interact with. ONC should also explore with the RCE and QHINs how data for compliance can be pulled automatically from the Participant's clinical flow and EHR.**