BlueCross BlueShield Association

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Donald Rucker, M.D.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted via the ONC Comment Submission Portal on HealthIT.Gov.

RE: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to respond to the Trusted Exchange Framework and Common Agreement (TEFCA Draft 2) released by the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) on April 19, 2019, on HealthIT.Gov.

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide healthcare coverage for one in three Americans. For more than 90 years, BCBS Plans have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBSA has extensive experience with data exchanges and interoperability as the operator of the BlueCard® program, one of the largest health claims processing and reimbursement programs in the nation, providing BCBS Plans seamless national access to 95 percent of physicians and 96 percent of hospitals that participate in BCBS healthcare networks.

As leaders in advancing data interoperability and consumer access, BCBSA and BCBS Plans have engaged in numerous initiatives to empower patients by providing online consumer tools, voluntary expansion of the Blue Button 2.0 initiative, and being a founding member in the Health Level 7 (HL7) Da Vinci Project for Fast Healthcare Interoperability Resources (FHIR) Application Programming Interface (API) standards development. BCBSA is also an active member in the Sequoia Project and the Creating Access to Real-Time Information Now (CARIN) Alliance. We support the efforts of the Sequoia Project, Carequality and RTI International to bring together stakeholders across the healthcare ecosystem to advance consumer data access and to build the interoperability framework. We also support the work by CARIN and its Common Payer

Consumer Data Set (CPCDS) workgroup to develop a trust framework for consumer-directed exchanges to help solve the policy, technical and adoption barriers to implementing FHIR-based APIs and meet the privacy expectations in health information exchange beyond the scope of the Health Insurance Portability and Accountability Act's (HIPAA) privacy and security regulations.

Informed by our experience, BCBSA believes actionable, secure, reliable and interoperable data that are shared through a trusted exchange will enable a higher quality, more efficient and effective healthcare delivery system. Upon review of TEFCA Draft 2, we offer the following feedback as top priorities and urge ONC to incorporate these recommendations in the final TEFCA Draft 2:

- ONC should clarify that meaningful choice based limits to data sharing should not infringe on covered entities' treatment, payment and healthcare operations (TPO) based uses of protected health information (PHI) and electronic health information (EHI).
- Cooperation and non-discrimination requirement to exchange EHI with all the stakeholders including business competitors should not apply to proprietary financial data.
- Health Information Networks (HINs) should not be allowed to collect, store, use and/or monetize consumer data, including proprietary financial information, such as negotiated rates, for unauthorized, undisclosed secondary purposes.
- No HIN should be allowed to make the release of proprietary data a condition of an individual authorization.
- ONC should provide a glide path, longer than 18 months, for Qualified Health Information Networks (QHINs) to comply with updates to US Core Data for Interoperability (USCDI) and changes in QHIN Technical Framework (QTF).
- ONC should support HL7 FHIR-based resources for the required QHIN functionalities and leverage the B2B HL7 Da Vinci use cases.
- QHINs should use a broader set of specified patient demographic elements to resolve patient identity issues and not require a centralized index or a single standardized approach for QHIN's patient matching efforts.

Thank you for the opportunity to comment on TEFCA Draft 2. In what follows, we expand on and offer additional detailed recommendations to advance these priorities. We welcome the opportunity to provide additional information on the more detailed recommendations discussed below. If you have any questions on our recommendations, please contact Lauren Choi, Managing Director, Health IT, at 202.626.8639 or lauren.choi@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Office of Policy and Representation

<u>BCBSA's Detailed Comments on TEFCA Draft 2</u>

<u>Trusted Exchange Framework Principles</u>

1. **Transparency: Conduct all exchange and operations openly and transparently.**

Issue: Meaningful Choice-based Data Sharing Restrictions

Principle 2.C.4 states HINs should provide a method by which individuals can exercise meaningful choice regarding the exchange of EHI as defined in the MRTC. The principle does not clarify the interaction of meaningful choice decisions about data use and sharing within the HIPAA permitted exception for the use and disclosure of PHI for treatment, payment and healthcare operations (TPO) purposes without obtaining specific use authorizations.

Recommendation #1:

ONC should clarify that principle 2.C.4 in no way infringes on covered entities' TPO-based uses of PHI.

Rationale:

HIPAA TPO exceptions are necessary for providers and payers to conduct the business of healthcare. This section, however, may result in unintended consequences of infringing on allowable TPO uses by placing controls around the use and disclosure of individually identifiable health care information (IIHI) that may fall outside and beyond the protection of HIPAA, i.e., IIHI created by or residing in an API or shared through a trusted exchange network. We ask that ONC clarify this section to make certain that here is no ambiguity between appropriate TPO uses and disclosures as permitted by law and situations beyond HIPAA protections that may be subject to the more individualized directives for data uses and sharing envisioned by meaningful choice based directives.

Recommendation #2:

Approaches to allow meaningful choice must be aligned to standards for communicating the choices and must also be aligned with the current and near-term capabilities of provider, payer and HIN technologies to support choice options.

Rationale:

The current state of metadata tagging of segments of a clinical record do not permit the level of granularity promised by the concept of providing meaningful choice to consumers about the disclosures and uses of discrete segments of their healthcare record. Until such time as the standards-based technological functionality has been tested and proven, the expectations of consumers will need to be managed regarding the limitations on the scope of their individualized personal data use choices.

2. **Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.**

Issue: Proprietary Data

BCBSA supports consumer transparency and agrees with the objective of this principle, which we understand to be to end the practice of engaging in and/or facilitating information-blocking behavior solely to gain commercial advantage. However, there are types of data in categories that are considered to be proprietary business information which, if required to be released, would create competitive disadvantages for the releasing entity.

Recommendation:

BCBSA recommends that:

- HINs should not be allowed to collect, store, use and/or monetize the consumer data, including proprietary financial information such as negotiated rates.
- No HIN should be allowed to make the release of proprietary data a condition of an individual authorization.
- No HIN or designated third party who serves as aggregator of data should be allowed to use proprietary financial information for unauthorized, undisclosed secondary purposes.
- There should be clarification that Participants or Participant Members may restrict disclosure (e.g., through masking of certain information) to protect proprietary and confidential information and/or trade secrets.

Rationale:

There is some data—by its nature or business purpose—that is inherently of competitive design or specifically for competitive use. To the extent that this information is IIHI or EHI that is being released pursuant to an individual's specific authorization, we believe such data should not be shared in a way or through a framework that puts the sharing entity at a competitive disadvantage. This would include compelling payers to release certain types of health plan proprietary data, e.g., negotiated rates and/or closed health services networks contracted prices with health plans.

3. **Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.**

Issue: Exercise of Meaningful Choice

Principle 4.B implies that in order to adhere to privacy policies, the HIN must ensure that providers and organizations participating in data exchange "have confidence" that individuals have the opportunity to exercise meaningful choice.

Recommendation:

ONC should redraft Principle 4. The principle should state that the HINs will ensure confidence that participating organizations are meeting their privacy and confidentiality obligations under applicable laws and regulations.

Rationale:

Adding references like “meaningful choice” results in a lack of clarity regarding how this term is defined and becomes problematic as participants may not define the term consistently. To start, ONC should work with stakeholders to develop guidance and scenarios to further define “meaningful choice” and “reasonable confidence”.

Minimum Required Terms and Conditions (MRTC)

1. Definitions

Issue: Breach Definition

In MRTC Section 1, the “breach” definition is the same as the HIPAA definition of a PHI breach but applies it to EHI on the actions or omissions by QHIN, Participant or Participant Member in their compliance with framework agreements. At the same time, it does not modify Federal Trade Commission (FTC) rules regarding a security breach.

Recommendation:

BCBSA recommends that the language should be limited to HIPAA and PHI, or alternatively EHI as incorporated into HIPAA.

Rationale:

The inclusion of EHI into a breach notification requirement opens the door to expansive notification requirements and obligations since EHI as defined here includes any individually identifiable health information (IIHI) that relates to past, present, or future health, conditions, healthcare and payment information for the provision of healthcare to the individual.

Issue: Exchange Purposes Definition

“Exchange purposes” is defined very broadly in the MRTC to mean the use or disclosure of EHI for treatment, utilization review, quality assessment and improvement, business planning and development, public health, individual access services and benefits determination, each to the extent permitted under applicable Law.

Recommendation:

BCBSA recommends that the definition of “business planning” and “development” be more narrowly and clearly defined inside the definition of exchange purposes as it affects EHI use or disclosure. ONC should also provide examples of the particular activities by HINs, their Participants, and Participant Members that will constitute business planning and development.

Rationale:

“The broadness of this definition implicates almost all healthcare electronic data exchange, creating a monopolistic data stream. The inclusion of business planning and development activities could also allow access by unauthorized individuals to proprietary, confidential or purely business related activities, putting businesses at a competitive disadvantage. The

participants' forced reliance on the QHIN for the transfer of this broad set of information could also create unfettered dependencies on the QHINs among providers, resulting in a potential barrier to delivery of healthcare services.

Issue: Meaningful Choice Definition

The MRTC "meaningful choice" definition states that the individual's choice regarding the use and disclosure of their EHI must be made with advance knowledge, not used as a condition of treatment and is revocable prospectively.

Recommendation:

The definition should be modified to clarify that the exercise of meaningful choice by an individual does not create an impediment for HIPAA covered entities to share PHI for TPO purposes.

Rationale:

The definition in this section fails to exempt HIPAA PHI from interference with a covered entity's right to share data for TPO purposes. In verbal responses to direct questions about the interaction of the meaningful choice with a covered entity's exercise of the TPO exception, ONC has been clear that covered entities are entitled to use or disclose the information in accordance with applicable laws. BCBSA believes that this TPO exception should be plainly stated in the definition of meaningful choice.

Issue: Minimum Information Definition

The MRTC definition of "minimum information" does not define disposition of data when the data access is completed or terminated.

Recommendation:

BCBSA recommends the addition of a description of what happens upon termination/completion of an action to use or disclose EHI, including secure deletion of PHI, when the intended delivery to the individual is complete. ONC should clarify that once the delivery of PHI to individual is complete, that any HIN or third party may not permanently store PHI or EHI of any kind in its system.

Rationale:

The minimum information definition places a substantial administrative burden upon the participants and participant members to specify to the individual the scope of EHI uses and disclosures and against which the information-sharing activities of the affected entity can later be measured for compliance. In addition to the ongoing burden of keeping such revelatory information current (i.e., the duration of the disclosure actions, to whom the disclosures are being made, etc.) there is the potential burden and security challenges around permanent storage of PHI.

Issue: Participant-QHIN Agreement and Participant Member Agreement Definitions

The MRTC definitions of Participant-QHIN and Participant Member agreements list the order of precedence in the event of a conflict between applicable laws. The list of documents in the order of precedence does not specifically reference the business associate agreement (BAA) between the parties (if applicable), but instead provides a general description of "any other terms and conditions agreed to by the parties."

Recommendation:

BCBSA recommends that the order of precedence list in the event of a conflict should specifically include, as the second document to govern in conflicts of laws or agreements, the required HIPAA BAA between the parties.

Rationale:

Without the specific reference to the BAA between the parties, the terms of any such BAA, including stricter time frames, could be overridden by potentially less stringent terms. Further, BAAs are required of covered entities and their business associates by federal and some state laws and regulations. Participant-QHIN agreements are part of a voluntary framework governing a private-sector data transmission network, to be qualified by a semi-private RCE under contract to a government agency. Therefore, the terms of the legally required BAA should take precedence over the voluntary framework-based Participant-QHIN agreement.

2. Initial Application, Onboarding, Designation and Operation of QHINs

Issue: Individual Exercise of Meaningful Choice

Subsection 2.2.3 specifically directs that a QHIN shall enable an individual's exercise of meaningful choice and requires QHINs to publish instructions on how an individual can exercise their meaningful choice. It does not specify, however, how QHINs should incorporate current TPO exceptions in its communications.

Recommendation:

BCBSA recommends that ONC develop and provide, in coordination with the U.S. Department of Health and Human Services (DHHS) Office of Civil Rights, more specific guidance regarding the interaction of the TPO exceptions under HIPAA and the meaningful choice process for ensuring individual directions for the use and disclosure of EHI is implemented by QHINs, Participants and Participant Members. Note this recommendation also applies to the similar circumstances required in subsections 7.3 and 8.3 for Participant and Participant Member obligations, respectively.

Rationale:

To the extent that a QHIN may also be a HIPAA-covered entity, this requirement to publish instructions regarding the individual's exercise of meaningful choice may confuse the individual with regard to PHI that the covered entity can disclose for HIPAA TPO purposes without the need for obtain the individual's authorization. Without further clarification and streamlining,

covered entities are faced with the untenable situation where their systems would have to distinguish PHI allowable for HIPAA TPO treatment versus the broader EHI required under meaningful choice, which creates almost unmanageable privacy policy compliance and administrative burden. Additionally, BCBSA is concerned that the meaningful choice directives under a voluntary TEFCA QHIN system threatens to swallow the longstanding HIPAA Privacy Rule exceptions for TPO use of PHI that has enabled the efficient delivery of healthcare treatments and services for the past 25 years.

Issue: Updates and Changes to QTF

Under MRTC subsections 2.2.5 and 2.2.9, a QHIN has 18 months to update and support changes to new, approved versions of the USCDI and updates to QTF.

Recommendation:

BCBSA recommends that ONC change the 18-month requirement to “as soon as practicable”.

Rationale:

BCBSA is concerned that 18 months is not a sufficient amount of time for the systems changes necessary to update to an annual change in the USCDI and changes to QTF. To operationalize new USCDI elements or changes to QTF, it requires multiple steps including development of HL7 FHIR implementation resources, real-world testing and deployment to scale among all those who are sending, receiving and facilitating the exchange of new data elements. As we commented on ONC’s *Interoperability and Information Blocking Proposed Rule*, the required implementation timelines should pace with standards development and deployment to scale capabilities to support the functionalities and data elements necessary for seamless exchange of data.

Issue: Termination of Participation in the Common Agreement

MRTC Subsection 2.2.12 details the disposition of EHI when a QHIN Common Agreement is terminated. The subsection does not describe what happens when an individual revokes their request to share EHI.

Recommendation:

BCBSA recommends that ONC add the description of the responsibilities of the QHIN, Participants and Participant Members to effectuate an individual’s revocation of a request to share EHI. We also recommend the process mirror the responsibilities of covered entities to effectuate a revocation of a HIPAA authorization to share PHI in a situation not covered by the TPO exception.

Rationale:

To provide consumer transparency about the disclosure and use of their EHI and to establish trust in QHIN-based exchanges, BCBSA believes it is imperative to clearly delineate not only the responsibilities for effectuating an individual’s directive to share EHI, but the actions and steps that can or should be taken to effectuate a revocation of that directive. To minimize

confusion among QHINs, Participants and Participant Members, the required actions should align with current HIPAA requirements.

3. Privacy, Security, and Patient Safety

Issue: Breach Notification Requirements

MRTC subsection 6.1.1 describes the breach notification requirements for QHINs consistent with HIPAA's requirements. This section, however, ignores those situations where QHIN also has a BAA with an entity and the applicability of such BAA terms.

Recommendation:

BCBSA recommends that ONC modify this section to specifically reference the applicability and legal precedence of a BAA with a QHIN versus those of another party whose EHI was affected.

Rationale:

BCBSA believes that without a reference in the MRTC subsection to the applicability and precedence of a BAA with a QHIN and another party whose EHI was affected, the requirements in the subsection could be interpreted to override BAA agreements. This recommendation is consistent with our earlier recommendation regarding the precedence of BAA agreements over QHIN framework based agreements.

Issue: Demand for Compulsory Disclosures

MRTC subsection 6.1.3 lacks clarity on confidentiality of those that provide EHI. The section describes how requests for disclosures by regulatory bodies, for instance, to a QHIN should be addressed. Under the subsection, the QHIN is only required to reasonably cooperate with the party making the request, in securing assurances that the disclosed EHI will be accorded confidential treatment.

Recommendation:

BCBSA recommends that the subsection be modified to require the QHIN to cooperate with the entity that contributed the EHI in securing these reasonable assurances.

Rationale:

BCBSA believes that the party most interested in seeking reasonable assurances would be the party that contributed the EHI. Therefore, the QHIN should identify and cooperate with that contributing entity regarding such assurances.

Issue: Other Legal Requirements Affecting the Sharing of EHI

The MRTC subsection generally sets the requirements on QHINs to comply with applicable laws, for example, requiring an individual's consent, prior to the use of his/her EHI. Specifically, it states that if applicable law requires that an individual consent to or approves the use or disclosure of EHI to the QHIN, then the QHIN shall not disclose such EHI except in compliance with applicable law.

Recommendation:

BCBSA recommends that the language in the subsection be modified to clearly indicate intent to govern the use or disclosure of EHI "by" the QHIN, not "to" the QHIN. This recommendation also applies to the similar circumstances required in subsections 7.4 and 8.4 for Participant and Participant Member obligations, respectively.

Rationale:

BCBSA believes that the current wording – "to the QHIN" – may be interpreted to mean that the obligation to comply with that other, applicable law is solely on the party disclosing the EHI to the QHIN rather than an obligation falling on the QHIN and subsequent sharing of the EHI by the QHIN.

Issue: Written Privacy Summary

This MRTC subsection requires QHINs to publish and make available a notice of privacy practices using the ONC's Model Privacy Notice, with additional information. This notice does not supplant the need for a HIPAA privacy notice. In situations where QHIN is also a HIPAA-covered entity, this subsection implies that the entity would have to create, maintain and distribute two separate privacy notices – a QHIN notice based on the ONC Model Notice and another HIPAA-complaint notice.

Recommendation:

BCBSA recommends that ONC offer guidance on how dual entities can reconcile these two separate requirements for privacy notices and how the entity may be able to create and offer only one, unified privacy notice to individuals. This recommendation applies to the similar requirements in subsections 7.6 and 8.6 for Participant and Participant Member obligations, respectively.

Rationale:

Duplicative written privacy notices may be confusing to individuals and represent an administrative burden to the affected entities.

Issue: Minimum EHI Security Requirements, Application of NIST Standards

The MRTC requires QHINs to comply with the NIST SP 800-171 Moderate Security controls.

Recommendations:

In addition to NISP SP 800-171, the Participants and Participants Members should be able to select nationally recognized cybersecurity frameworks, such as HITRUST, ISO 27001 to demonstrate compliance with the HIPAA security rule.

Rationale:

HITRUST and ISO 27001, in addition to NIST SP 800-171, are nationally recognized non-governmental security frameworks used by stakeholders to secure their information. MRTC should, therefore, allow use of nationally recognized frameworks currently in use today.

Issue: User Authentication

This section requires Participant Member or individual user that request EHI through QHIN be authenticated at a minimum of Identity Assurance Level 2 (IAL2) standard.

Recommendation:

BCBSA recommends that the Identity Proofing and Authentication/Authorization requirements are communicated to the Participants and Participant Member before these requirements are formalized.

Rationale:

The identity requirements outlined in NIST SP 800-63b will be burdensome to implement without the appropriate implementation planning, testing and implementation to all the stakeholders participating in TEFCA.

4. Right to Receive Summary of Disclosures of EHI

Issue: Content of Summary of Disclosures of EHI

Under MRTC Section 9, the individual is provided a right to request of QHINs, Participants and Participant Members a summary of their EHI disclosures for applicable exchange purposes for a period of up to six years immediately prior to the date of the request. Subsection 9.5.2 specifically details the content of the summary, which aligns with the HIPAA accounting of disclosures requirements at 45 CFR §164.528(b) (1) & (2). Covered entities complying with the HIPAA requirements are deemed in compliance with this subsection. However, the 45 CFR §164.528(b) (3) provision for reporting multiple disclosures to the same person or entity for the same individual is not included in subsection 9.5.2.

Recommendation:

BCBSA recommends that subsection 9.5.2 should be fully aligned with 45 CFR §164.528 so that individuals requesting a disclosure summary receive the same content and format regardless of whether the QHIN is a HIPAA-covered entity.

Rationale:

BCBS Plans report that they already face challenges as the providers do not designate whether they are HIPAA covered entities or are providers subject to the consent restrictions of the substance use disorder treatment information disclosures under 42 CFR Part 2. We believe that a QHIN would face similar confusion in determining what laws are applicable to the EHI unless the provider provides their coverage status.

<u>QHIN Technical Framework (QTF)</u>

1. Example QHIN Scenarios

Issue:

The QTF Section 2 presents sample QHIN exchange scenarios illustrating basic workflows about a real-world use case and describing the various functions performed by QHINs to enable information exchange through the QHIN Exchange Network.

Recommendation:

ONC should provide broader exchange examples within the ecosystem beyond provider centric use cases. In expanding the scenarios, we recommend that ONC leverage the B2B HL7 Da Vinci use cases including prior authorization, medication reconciliation and care coordination to start.

Rationale:

The current examples are provider-centric examples despite ONC's acknowledgment that this section is not representative of all possible workflows or use cases. By providing sample use cases representative of diverse exchange uses, it would demonstrate the potentially broad functionalities of QHINs within the network.

2. Functions and Technology to Support Exchange

Issue:

QTF section 3 outlines a QHIN's functions and applicable standards and implementation approaches. In areas where the industry has not coalesced around a single standard or preferred approach, the QTF outlines the high-level technical function(s) that QHINs must support and seeks comment on which standards the QTF should specify.

Recommendation:

BCBSA recommends that ONC support HL7 FHIR resources to support QHIN functionality.

Rationale:

Identifying the standards for the primary QHIN scenarios is a critical element of interoperability for the industry. BCBSA understands that there are a narrow set of standards applicable to the QHIN functions, primarily from the standards development organizations such as the Integrating Healthcare Enterprise (IHE) and HL7. ONC should be specific about which standards are being used and support HL7 FHIR based resources to support data exchange.

Issue: Patient Identity Resolution

This subsection seeks information on whether QHINs should use broader set of patient demographic elements to solve for patient identity since the IHE's Cross-Community Patient Discovery (XCPD) profile only requires a minimal set of demographic information (i.e., name and birth date/time.) It also asks about the various approaches to identity resolution, whether

ONC should name a single standardized approach to patient identification, and whether QHINs should set minimum performance standards.

Recommendation:

QHINs should use a broader set of specified patient demographic elements to resolve patient identity issues and use the USCDI process to standardize the requirements. ONC should not require a centralized index or repository of patient identity information or a single standardized approach for the QHIN's patient matching efforts, while setting minimum performance standards.

Rationale:

USCDI, as the standard data set for EHI, would be the appropriate vehicle to build out and standardize the set of demographic data elements needed for patient matching. Additionally, given the opportunity to innovate through a competitive marketplace for secure identity solutions, it is essential that ONC recognize varying identity requirements, i.e. payment versus treatment purposes, while providing a baseline performance standards such as matching accuracy rates, to raise the bar on exchange quality and patient privacy and security.