

**David Schwartz**  
Head of Global Policy  
Global Public Policy & Government Affairs



June 17, 2019

VIA ELECTRONIC SUBMISSION TO <http://www.HealthIT.gov>

Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
330 C Street, SW  
Floor 7  
Washington, DC 20201

701 Pennsylvania Avenue, NW  
Suite 720  
Washington, DC 20004  
[David.Schwartz@Cigna.com](mailto:David.Schwartz@Cigna.com)

**Re: Trusted Exchange Framework and Common Agreement Draft 2**

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the Trusted Exchange Framework (TEF) and Common Agreement (CA) (collectively TEFCA) Draft 2 issued by the Office of the National Coordinator of Health Information and Technology (ONC) of the Department of Health and Human Services (HHS or the Department) related to the 21st Century Cures Act (the Act). In section 4003 of the Act, Congress directs ONC to develop or support a TEF, including a CA among health information networks (HINs) nationally. We appreciate ONC's goals in this endeavor: to provide a single "on-ramp" for nationwide connectivity, enable electronic health information (EHI) to securely follow the patient where and when it is needed, and support nationwide scalability in developing a Trusted Exchange Network (TEN), TEF, and CA.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as "Cigna"), is a global health service organization dedicated to helping people improve their health, well-being, and peace of mind. Our subsidiaries are major providers of medical, pharmacy, dental, disability, life and accident insurance, and related products and services, with over 160 million customer relationships in the more than 30 countries and jurisdictions in which we operate.

Cigna completed its merger with Express Scripts in December 2018, bringing together approximately 74,000 employees around the world. The combination integrates two complementary companies, each with industry-leading cost trend capabilities, which together are positioned to deliver better care, expanded choice, and drive down health care costs. The combined company's medical, clinical, pharmacy, behavioral and wellness insights empower us to deliver improved affordability, choice and predictability through connected, personalized solutions to advance whole person health.

Within the U.S., Cigna provides medical coverage to approximately 14.3 million Americans in the commercial segment. We also provide coverage in the individual insurance segment in several states, both on- and off-Exchange, to about 306,000 people. Additionally, Cigna, together with our Express Scripts subsidiary, serves approximately 4.2 million people through our Medicare Advantage, Medicare Prescription Drug Program and Medicare Supplemental products.

With that context as background, Cigna offers the following comments on the TEFCA Draft 2 and its complementary documents: TEF Draft 2, the Minimum Required Terms and Conditions (MRTC) Draft 2, and Qualified Health Information Network (QHIN) Technical Framework (QTF) Draft 1.

\* \* \*

## **I. TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT DRAFT 2**

The ONC Information Blocking Proposed Rule would require health care providers, health information technology (IT) developers, health information exchanges (HIEs), and HINs to join a TEN as defined by TEFCA. The companion proposed rule on interoperability and patient access issued by CMS would require Medicare Advantage organizations (including MA-PD plans), Medicaid managed care plans, Children's Health Insurance Program managed care entities, and Qualified Health Plan issuers in the Federally-facilitated Exchange to participate in a TEN. The ONC and CMS proposed rules both identify the following criteria for TENs:

- The TEN must be able to exchange protected health information, as defined in 45 CFR § 160.103, in compliance with all applicable state and federal laws across jurisdictions.
- The TEN must be capable of connecting both inpatient and ambulatory electronic health records (EHRs).
- The TEN must support secure messaging or electronic querying by, and between, patients, providers, and payers.

We support ONC's efforts to establish a framework for trusted exchange of EHI with a CA, but we also believe more needs to be done to encourage exchange of health information through interoperable systems to support care coordination, care management, and population health. For example, appropriate governance will be necessary to scale the functioning system of connected HINs by ONC with a Recognized Coordinating Entity (RCE). We recommend an open and transparent approach between payers and the ONC and RCE in the development of the TEF and CA. We support a technical architecture that creates a "network of networks" QHIN structure, with multiple points of entry. This will allow payers to determine the appropriate level of TEN participation. Furthermore, we encourage CMS and ONC to provide payers and other entities sufficient time to comply with this requirement.

ONC requests comments on three data exchange modalities: QHIN Targeted Query, QHIN Broadcast Query, and QHIN Message Delivery. Cigna agrees the CA should support these exchange modalities and purposes for sending and receiving EHI. We also recommend including pull modalities in the MRTCs Draft 2 to allow for greater flexibility for data exchange.

## **II. APPENDIX 1: TRUSTED EXCHANGE FRAMEWORK**

We support the vision of the TEF to provide an "on-ramp" to connectivity nationwide, enable EHI to securely follow the patient when and where it is needed, and support nationwide scalability. We believe this cannot be accomplished in the near term, but will take several years to achieve. We also recognize the principles of the TEF (standardization; transparency; cooperation; non-discrimination; privacy, security, and patient safety; access; and data driven accountability) are intended to assist all stakeholders, and are foundational to a well-functioning HIN. We are concerned, however, these principles are not binding on Participants, so Cigna recommends incorporating them as conditions in the CA.

We recommend payers should have the option to join a TEN, but that it not be mandatory at this time. The July 1, 2020 effective date for requiring payers to participate in a TEN is not attainable today. The timeframe for payers is too aggressive and should be delayed until January 1, 2022 or later. More efforts are needed before payers can successfully participate in a TEN, such as:

- ONC and the new RCE will need to include payers in the creation and review process of the CA.
- Suitable QHINs do not currently exist. The ability to exchange information between them in a way to meet the technology requirements of TEFCA Draft 2 and state regulations is yet to be determined.
- Payers need time to evaluate if QHINs, HIEs, and HINs can meet their geographic requirements and determine if they have the technical ability to scale their systems to meet payers' needs to participate in a TEN.
- Payers need to understand the technical and financial requirements for joining a TEN.
- Exchange standards are still not fully available or tested to support payer-to-payer data exchange through the TEN.
- United States Core Data for Interoperability (USCDI) does not currently meet payer data exchange requirements. Clarification is requested if all Participants, Participant Members, and QHINs will be required to share USCDI, or if only QHINs or QHIN and their TEN Participants will share.
- Additional information is needed on how the RCE will monitor QHINs and ensure payers' members' data is being protected and utilized correctly.

We request ONC and CMS allow payers, providers, and industry stakeholders appropriate time to evaluate and test the TEFCA with all of its enabling components in a transparent manner before requiring payers and providers participate in a TEN.

### **III. APPENDIX 2: MINIMUM REQUIRED TERMS AND CONDITIONS DRAFT 2**

Cigna supports TEFCA's approach to protecting individual privacy while promoting efficient data exchange. The MRTC's minimum privacy requirements are measured and manageable across a variety of Participant organizations, which will promote greater involvement across care settings. This baseline framework keeps Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy compliance at the forefront while leaving QHINs and Participants room to develop privacy compliance controls appropriate to their respective businesses.

We provide the following additional comments on the MRTC Draft 2 provisions:

#### **Meaningful choice**

MRTC provisions regarding meaningful choice are warranted additions to the TEFCA Draft 2 and substantially align with Cigna's existing privacy practices. Section 7.3 of the MRTC requires Participants to respect an individual's request not to use or disclose patient EHI in connection with the CA unless applicable law requires the Participant to make such use or disclosure. Cigna, in accordance with HIPAA's individual rights provisions, already has processes in place to address an individual's request to restrict the uses and disclosures of patient health information. This MRTC requirement would be a natural expansion of the process. However, HIPAA does not impose a timeframe under which a covered entity must accommodate an individual's restriction request. Section 7.3 would require Cigna to communicate the individual's request back to the QHIN within five business days "after receipt" of the request. With the introduction of TEFCA, restriction requests may quickly increase, and this short timeframe could pose a considerable administrative burden on

Participants. Therefore, we recommend ONC increase the timeframe to 15 business days “after receipt” of the request.

#### **Written privacy summary**

Section 7.6 notes the privacy summary does not “supplant the HIPAA Privacy Rule obligations of a Participant which is a Covered Entity to post and distribute a Notice of Privacy Practices meeting the requirements of 45 CFR § 164.520.” This seems to suggest the privacy summary and the Notice of Privacy Practices (NPP) are intended to remain two separate documents. We recommend ONC combine the summary and the NPP into one document – *i.e.*, for the NPP to have a dedicated section on using and disclosing health information in connection with the CA, thus providing individuals the information they need regarding Participants’ privacy practices in one single document.

#### **Breach notification requirements**

The MRTC’s expansion of the HIPAA breach notification requirements to CA Participants who are neither business associates nor covered entities is necessary to foster trusted data exchange. As a HIPAA-covered entity, Cigna will need assurances to fulfill our reporting of breach obligations even when transacting with entities historically not subject to health care privacy laws. Prompt breach notification remains paramount as reporting deadlines pose a common compliance obstacle. The MRTC encourages early notification to QHINs and other Participants who may be impacted by a breach – an increasingly important sentiment with the rise of aggressive, state-based breach reporting timeframes.

### **IV. APPENDIX 3: QUALIFIED HEALTH INFORMATION NETWORK TECHNICAL FRAMEWORK DRAFT 1.**

We support a common set of standards for QHIN-to-QHIN exchange of EHI. Cigna recommends the standards to connect to all QHINs be the same as Participant and Participant Members may join different QHINs. A Participant or Participant Member may wish to join and connect to multiple QHINs, so using a common set of standards would minimize the burden of meeting of varying standards potentially required by QHINs.

#### **Standards**

One suggested standard in the QTF Draft 1 is the USCDI. In the ONC Information Blocking Proposed Rule, ONC proposes to adopt a new §170.213: “Standard. United States Core Data for Interoperability (USCDI), Version 1 (v1) (incorporated by reference in §170.299),” Preamble FR Citation: 84 FR 7441. Furthermore, ONC proposes to revise the following 2015 Edition certification criteria to incorporate the USCDI standard in place of the “Common Clinical Data Set” (currently defined at §170.102 and proposed for removal in this rule):

- “Transitions of care” (§170.315(b)(1));
- “View, download, and transmit to 3rd party” (§170.315(e)(1));
- “Consolidated CDA creation performance” (§170.315(g)(6));
- “Transmission to public health agencies—electronic case reporting” (§170.315(f)(5)); and
- “Application access—all data request” (§170.315(g)(9)).

We support improving care transitions through the electronic exchange of data. This cannot be accomplished unless changes are made to the current USCDI v1. In our comments on ONC’s proposed rule, we recommended ONC address certain issues when finalizing the proposed rule. We reiterate those recommendations here:

- Current USCDI v1 standards do not support the necessary data elements for payer-to-member, payer-to-payer, and payer-to-provider exchange of data. The USCDI v1 needs to be expanded to support these requirements.
- The USCDI payer resources, including coverage (for member identification and plan identification); remittance advice (for Blue Button 2.0 support); claim (for prior-authorization support); device; endpoint; and required data element items for provider directory, and payer networks, should be published concurrent with the final rule to help payers identify elements needed to be compliant.
- Allow the industry time to develop and achieve consensus on the USCDI or another standard data set in order to meet the interoperability requirement.

The QTF Draft 1 also references electronic prescribing standards. Those standards are developed by the National Council for Prescription Drug Programs (NCPDP) in collaboration with stakeholders. TEFCA requires the exchange of prescription drug information with the QHINs and within the TEN. We recommend ONC collaborate with the NCPDP to explore the open API Fast Healthcare Interoperability Resources (FHIR) standards specific to the Health Level 7 (HL7) Da Vinci Project for a January 2022 or later effective date for electronic prescribing. This will also facilitate the exchange of prescription drug information for patients.

ONC requested comment on specific standards and we offer the following in response:

#### **Question #4 – Query Function**

*ONC Question -The Query function per ONC describes a general workflow and set of capabilities for QHINs conducting query-based, inter-network document exchange. However, implementation 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<sup>49</sup> 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.*

Cigna understands application programming interfaces (APIs) define the contacts for data inputs and outputs. The interpretation of the data labels and values for identifying the data used as inputs/outputs is important. Our concern is what happens when a targeted query has an unknown address (*i.e.*, a provider sees a patient for the first time). We ask ONC to advise how payers will be able to locate a provider's QHIN without a data label for the address.

#### **Question #5 – IHE XCA**

*ONC Question – "The IHE XCA profile supports a number of defined queries (e.g., FindDocuments, GetAll, GetDocuments, GetRelatedDocuments, etc.). Each query includes a number of optional parameters. Should the QTF specify which queries/parameters a QHIN must support? Which queries/parameters are most widely implemented and/or useful today?"*

Cigna recommends the QTF should specify which queries/parameters a QHIN must support to allow Participants to know what information is available and how best to retrieve it.

#### **Question #6 – IHE XCA - discrete data queries**

*ONC Question – "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.”*

ONC does not require APIs to follow the RESTful standard in its proposed rule, despite IT developers in other industries being required to do so. Therefore, Cigna requests ONC adopt FHIR Release 4 (or the most current version available at time of final rule publication) for APIs.

### **Questions #7 - 9 – Patient Matching**

*ONC Question – “We believe the role of ONC and the RCE is to facilitate and set a floor for innovation, but not restrict private sector solutions. As it relates to patient matching, we recommend flexibility to continue to iterate solutions to identify and match patient records, including the development of objective measurements of patient identity accuracy.”*

Cigna and Express Scripts have had success with patient matching with internally-developed solutions. These solutions have produced significant improvements in patient safety. We would be glad to discuss our patient matching success with ONC.

We recommend ONC work with the RCE and CMS to advance standardization of demographic information, such as applying the United States Postal Service (USPS) standard to addresses, or adding new data elements such as email address. Research funded by the Pew Charitable Trusts and published recently in the *Journal of the American Medical Informatics Association* revealed the standardization of addresses would improve match rates by approximately three percent, while standardizing last name to the standard used by the Council for Affordable Quality Healthcare would further improve match rates up to eight percent.<sup>1</sup> These findings suggest match rates could be further improved if ONC required use of USPS standards for address by health care organizations and within the USCDI. Consistent with Pew’s recommendations, we recommend ONC work with CMS to standardize other demographic information.

ONC could also rely on industry collaboration to build on best practices or minimum assurance rates. These solutions could include leveraging patient authorization information, improving existing processes for storing a patient’s identification card at the provider’s office, or implementing public-private partnerships similar to those that have successfully solved person-matching issues in other industries (e.g., the airline industry and Transportation Security Administration (TSA) security check process).

One concept being worked on by the ONC FHIR Patient Matching Task Force is to use a token authentication process to verify a patient identity similar to the TSA. This process would make a patient’s identification fully digitalized and available in a common identity format. Providers would be able to electronically scan and capture a record provided by Medicare, Medicaid, or a commercial insurer and store a record in the patient’s EHR. This would allow the provider to authenticate and verify the patient. Then, when the payer or provider use an API to request data from another plan, they would use the patient’s unique token. This process would be very similar to the identification pattern used today by the airlines. Each airline has agreed to use a common identity format to match the person associated with a boarding pass. This idea could be extended successfully to a health industry model if all stakeholders loaded all persons’ eligibility identity into a shared repository as a stakeholder cooperative project. If all payers loaded their data into a CMS-sponsored repository, we could use identification token matching technology to verify patients.

---

<sup>1</sup> Shaun J Grannis et al., “Evaluating the effect of data standardization and validation on patient matching accuracy,” *Journal of the American Medical Informatics Association* 26, no. 5 (May 2019): 447–456, <https://doi.org/10.1093/jamia/ocy191>

An ONC-convened stakeholder group may also be able to identify minimum assurance rates, which would vary by setting. For example, the level of assurance of accurate patient matching needed for administrative or payment information would be lower than the level of assurance needed for treatment. We further recommend CMS and ONC adopt a safe harbor for entities following best practices or meet the assurance rates with privately developed solutions.

#### **Question #10 - Record Locator Services**

*ONC Question – “Recognizing there are different ways to implement Record Location Services, should the QTF specify a single standardized approach across QHINs?”*

Cigna believes a single standard may not be required as long as results can be found as requested when data is queried.

#### **Question #11 – Directory Services**

*ONC Question – “Should the QTF require QHINs to implement Directory Services? Recognizing there are many possible approaches for implementing Directory Services, should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly accessible?”*

Cigna believes the QTF should require QHINs to implement Directory Services. Cigna recommends the QTF specify a single standardized approach for Directory Services.

#### **Question #14 – Auditing**

*ONC Question – “QHINs may participate in a variety of activities and transactions involving First Degree Entities and/or internal operations, including receiving and processing Query and Message Delivery Solicitations, performing Patient Identity Resolution, performing Record Location, sending EHI, receiving EHI, performing queries, granting/revoking access credentials, etc. Future versions of the QTF may specify a list of events a QHIN must record involving First Degree Entities and/or internal operations. Which activities and transactions should the QTF specify as auditable events? What information should the QHIN record about each event?”*

Cigna recommends the following information should be recorded by the QHIN about each of the events below:

- Query and Message Delivery – The solicitation should audit the number of matches received versus number of matches where an action was taken and recorded.
- Patient Resolution – Details on all attempts to match patients; success rate and “confidence scores,” including Demographic Sustainability and European Integration information and data used to attempt the match, should be recorded.
- Record Location – Number of patient matches attempted and number of successful matches should be recorded.
- Sending EHI – Patient, type of data sent, reason, who the information went to if it was a targeted to a specific patient should be recorded.
- Receiving EHI – Patient, type of data, who sent the data, and who received the data should be recorded.
- Granting/Revoking Access – Full detailed information should be recorded.

#### **Question #15 – Error Handling QTF**

*ONC Question – “Should the QTF specify a consistent set of error messages for interactions between QHINs? Which error messages should the QTF specify? Should the QTF specify a consistent format for*

*error messages?*” Cigna recommends the QTF specify a consistent set of error messages for interactions between QHINs. Cigna suggests any error messages used should be similar in format to X12 Electronic Data Standard Interchange Response and Acknowledgement Transactions.

## V. SUMMARY

Cigna strongly supports giving patients access to their health information and preventing information blocking. We support the principles of TEFCA Draft 2 and believe they should be binding for Participants and Participant Members.

In summary, we suggest the following recommendations:

*Revise the implementation date* – We believe the implementation timeline is too aggressive. The industry needs time to develop, implement, and test the standards, applications, and IT systems required to support a TEF and CA to exchange EHI in a TEN. We also would like to reduce the potential for unnecessary burden for payer and provider organizations to connect with a TEN and meet the requirements of a CA. We also suggest ONC and CMS consider developing one implementation timeline across proposed rules and align the creation of TEFCA and TEN to prevent undue burden to payers, providers, and other industry stakeholders.

*Continue piloting standards* – We encourage ONC to develop and fund demonstration projects with CMS and industry standards development organizations to ensure standards are fully developed to support both the ONC and CMS proposed rules and TEFCA as the technical specifications are reliant on each other and cross-referenced. We support improving care transitions through the electronic exchange of data elements, but this cannot be accomplished unless changes are made to the current USCDI v1 standard.

*Minimum Required Terms and Conditions* – Cigna supports TEFCA’s approach to protecting individual privacy while promoting efficient data exchange. We recommend alignment with HIPAA to accommodate an individual’s restriction request. We recommend ONC combine the summary and the NPP into one document.

*Make TEFCA voluntary for payers* – We recommend the requirement for payers to join a TEN be voluntary until TEFCA is tested and fully operational. Payers, including Cigna, are already exchanging health information with their customers. Prescribing how this should be accomplished may slow down innovative solutions already being developed. The timeframe for providers, health IT developers, HIEs and HINs is also too aggressive and should be delayed until January 1, 2022 or later.

Thank you for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you.

Respectfully,



David Schwartz