



June 17, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St. SW Floor 7
Washington, D.C. 20201

Dear Dr. Rucker:

The Confidentiality Coalition (Coalition) appreciates the opportunity to comment on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2 released by the Office of National Coordinator for Health Information Technology (ONC). We applaud the vision of this framework and ONC's leadership on advancing nationwide interoperability.

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others founded to advance effective patient confidentiality protections. The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

As ONC continues to work toward nationwide interoperability, we offer the following high-level comments on TEFCA Draft 2:

Meaningful Choice

For the last 20 years, the HIPAA privacy standards have engendered consumer trust. The Coalition believes that TEFCA and all policies, and procedures developed by the Recognized Coordinating Entity should align with the Health Insurance Portability and Accountability Act (HIPAA), including the presumed consent for the exchange of protected health information for treatment and minimum necessary information exchange for payment and health care operations. We agree with ONC in that individuals should have the opportunity to understand and make informed choices about where, how, and with whom their electronic health information is shared, however we suggest that ONC define Meaningful Choice in a way that applies only to the exchange of health information that does not fall under the definitions of treatment, payment and operations (TPO) as established by HIPAA. Establishing a new choice standard for TPO would be inappropriate for HIPAA Covered Entities and Business Associates,

as the current implied consent model for TPO is an ingrained standard that has served patients well. We ask that ONC clarify that Meaningful Choice applies to data sharing that is *not* contained within the HIPAA TPO construct. This clarification is essential for HIPAA Covered Entities' and Business Associates' participation in TEFCA.

Exchange Purposes

While there are a broad range of use cases for health information exchange, the Coalition agrees with ONC in prioritizing information exchange under TEFCA to Individual Access Services and a subset of Payment (Utilization) and Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development) as defined in the HIPAA Privacy Rule. We applaud ONC's intention to phase in new Exchange Purposes in the Common Agreement to support additional use cases.

Security Labeling

Coalition members are concerned with the way TEFCA proposes to treat sensitive data – requiring security metadata labeling for four types of data without taking into account the reality of differing state law approaches. The metadata tagging proposed in TEFCA could result in insufficient information being tagged in some states, and too much information tagged in other states. The Coalition has long held that physicians need access to all of a patient's information to provide safe and effective care. The Coalition recommends that ONC encourage further discussion among state governors to harmonize state privacy laws concerning health information, which would greatly improve trusted exchange between Qualified Health Information Networks (QHINs).

USCDI/Designated Record Set

The Coalition supports the requirement that QHINs have participants that are actively exchanging data included in the U.S. Core Data for Interoperability (USCDI) in a live clinical environment. Limiting trusted exchange to USCDI or the designated record set as defined in HIPAA allows for functionality and for growth of the data exchanged over time in a standard manner and also supports patient retrieval and contribution. It is important to note that USCDI does not currently meet payer data exchange requirements. With that in mind, we respectfully request clarification from ONC as to whether all users, Participants, Participant Members, and QHINs will be required to share USCDI, or if only QHINs or QHINs and their Trusted Exchange Network participants will share.

Summary of Disclosures

ONC has proposed that individuals have “the right to receive a summary of Disclosures of EHI for applicable Exchange Purposes for up to six years immediately prior to the date on which the summary of disclosures is requested.” An individual could request such summary from any QHIN, Participant, or Participant Member with which the individual has a direct relationship and the information must be provided within 60 days. Coalition members believe this proposal should apply only to entities whose services interact directly with patients and that such a summary of disclosures is only feasible if the information is electronically tracked and maintained in structure format by a QHIN. A Participant or Participant Member would not have access to the information on the various disclosures from the QHIN or other Participants or Participant Members. The Coalition urges ONC to clarify that responding to such requests, including compiling and maintaining the information necessary for such responses, rests solely with the QHINs.

Additional Recommendations

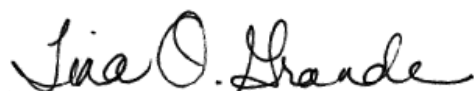
Additionally, as required by the 21st Century Cures Act (Cures), we ask that ONC undertake and implement pilots as part of the TEFCA implementation, starting with high priority exchange purposes such as exchange of information for individual access and treatment followed by subsequent phases that focus on a subset of payment and health care operations. ONC should consider integrating such pilots as part of the envisioned QHIN onboarding and cohort processes as mentioned in the Recognized Coordinating Entity (RCE) notice of funding opportunity. We urge ONC to clarify plans for QHIN cohorts. Furthermore, we recommend that ONC provide additional details about the technical assistance to be provided by ONC with the National Institute of Standards and Technology (NIST) as required in Cures. Pilot testing and technical assistance are essential to efficient and successful TEFCA implementation. Pilot testing would provide an opportunity to implement the new TEFCA processes on a smaller scale and receive input and feedback from participants. Weaknesses or shortcomings can then be addressed before implementation nationwide.

Furthermore, as healthcare systems begin to transform and solidify interoperability protocols, federal and state authorities will need clarity regarding appropriate enforcement for the entities under their jurisdiction. As a primary matter, entities covered by HIPAA currently have a well-understood process for oversight, interpretations, and enforcement. As new entities become involved with health information exchange, these jurisdictional and enforcement parameters are untested and unknown. ONC and other involved federal agencies such as the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR), the Centers for Medicare and Medicaid Services (CMS), the Federal Trade Commission (FTC) and others will need to work with public and private entities so that a common understanding is built for what rules and authorities govern in which scenarios and situations.

Finally, given the significant impact of TEFCA on advancing interoperability and information sharing in conjunction with ONC's and CMS' proposed rules on interoperability and patient access, the Coalition asks ONC to consider formal rulemaking for TEFCA to better ensure coordination between CMS and ONC and stakeholder participation.

We appreciate the opportunity to comment on this important proposal. Please contact me at tgrande@hlc.org or Devon Adams at dadams@hlc.org if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Tina O. Grande". The signature is written in a cursive, flowing style.

Tina O. Grande
Chair, Confidentiality Coalition and
Senior VP, Policy, Healthcare Leadership Council



ABOUT THE CONFIDENTIALITY COALITION

The Confidentiality Coalition is a broad group of organizations working to ensure that we as a nation find the right balance between the protection of confidential health information and the efficient and interoperable systems needed to provide the very best quality of care.

The Confidentiality Coalition brings together hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, clinical laboratories, home care providers, patient groups, and others. Through this diversity, we are able to develop a nuanced perspective on the impact of any legislation or regulation affecting the privacy and security of health consumers.

We advocate for policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, supporting policies that enable the essential flow of information that is critical to the timely and effective delivery of healthcare. Timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

Membership in the Confidentiality Coalition gives individual organizations a broader voice on privacy and security-related issues. The coalition website, www.confidentialitycoalition.org, features legislative and regulatory developments in health privacy policy and security and highlights the Coalition's ongoing activities.

For more information about the Confidentiality Coalition, please contact Tina Grande at tgrande@hlc.org or 202.449.3433.



CONFIDENTIALITY COALITION

MEMBERSHIP

AdventHealth
Aetna, a CVS Health business
America's Health Insurance Plans
American Hospital Association
American Society for Radiation Oncology
AmerisourceBergen
Amgen
AMN Healthcare
Anthem
Ascension
Association of American Medical Colleges
Association of Clinical Research Organizations
athenahealth
Augmedix
Bio-Reference Laboratories
Blue Cross Blue Shield Association
BlueCross BlueShield of North Carolina
BlueCross BlueShield of Tennessee
Cardinal Health
Cerner
Change Healthcare
Children's Hospital of Philadelphia (CHOP)
CHIME
Cigna
Ciox Health
City of Hope
Cleveland Clinic
College of American Pathologists
Comfort Keepers
ConnectiveRx
Cotiviti
CVS Health
Datavant
dEpid/dt Consulting Inc.
Electronic Healthcare Network Accreditation Commission
EMD Serono
Express Scripts
Fairview Health Services
Federation of American Hospitals
Genetic Alliance
Genosity
Healthcare Leadership Council
Hearst Health
HITRUST
Intermountain Healthcare
IQVIA
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Kaiser Permanente
Leidos
Mallinckrodt Pharmaceuticals
Marshfield Clinic Health System
Maxim Healthcare Services
Mayo Clinic
McKesson Corporation
Medical Group Management Association
Medidata Solutions
Medtronic
MemorialCare Health System
Merck
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National Association for Behavioral Healthcare
National Association of Chain Drug Stores
National Community Pharmacists Association
NewYork-Presbyterian Hospital
NorthShore University Health System
Pfizer
Pharmaceutical Care Management Association
Premier healthcare alliance
SCAN Health Plan
Senior Helpers
State Farm
Stryker
Surescripts
Teladoc Health
Texas Health Resources
Tivity Health
UCB
UnitedHealth Group
Vizient
Workgroup for Electronic Data Interchange
ZS Associates



PRINCIPLES ON PRIVACY

1. All care providers have a responsibility to take necessary steps to maintain the confidentiality and trust of patients as we strive to improve healthcare quality.
2. The framework established by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule should be maintained. HIPAA established a uniform framework for acceptable uses and disclosures of individually-identifiable health information within healthcare delivery and payment systems for the privacy and security of health information to enable the provision of health care services to patients. HIPAA follows the widely accepted Fair Information Practices standards (FIPS.)
 - a. The HIPAA Privacy Rule, through “implied consent,” permits the sharing of medical information for specified identified healthcare priorities which include treatment, payment and healthcare operations (as expected by patients seeking medical care.) This model has served patients well by ensuring quick and appropriate access to medical care, especially in emergency situations where the patient may be unable to give written consent.
 - b. The HIPAA Privacy Rule requires that healthcare providers and health plans limit disclosure of protected health information to the minimum necessary to pay for healthcare claims and other essential healthcare operations. This practice provides privacy protection while allowing for continued operations. Minimum necessary is relatively easy and simple to administer and practice.
3. Personal health information must be secured and protected from misuses and inappropriate disclosures under applicable laws and regulations.
4. Providers should have as complete a patient’s record as necessary to provide care. Having access to a complete and timely medical record allows providers to remain confident that they are well-informed in the clinical decision-making process.
5. Privacy frameworks should be consistent nationally and across sectors so that providers, health plans, and researchers working across state lines and with entities governed by other privacy frameworks may exchange information efficiently and effectively in order to provide treatment, extend coverage, and advance medical knowledge, whether through a national health information network or another means of health information exchange.
6. The timely and accurate flow of de-identified data is crucial to achieving the quality-improving benefits of national health information exchange while protecting individuals’ privacy. Federal privacy policy should be consistent with the HIPAA regulations for the de-identification and/or aggregation of data to allow access to properly de-identified information. This allows researchers, public health officials, and others to assess quality of care, investigate threats to the public’s health, respond quickly in emergency situations, and collect information vital to improving healthcare safety and quality.
7. For the last 20 years, the HIPAA privacy standards have engendered consumer trust. Any future legislation or rulemaking that addresses identifiable health information should conform with consumers’ expectations.