



February 15, 2018

The Honorable Donald Rucker, MD
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted electronically at: exchangeframework@hhs.gov

Re: Draft Trusted Exchange Framework and Common Agreement (TEFCA)

Dear Dr. Rucker:

The Alliance for Nursing Informatics (ANI) and the American Nurses Association (ANA) appreciate the opportunity to comment as nursing stakeholders on ONC's Draft Trusted Exchange Framework and Common Agreement (TEFCA). We will provide comments to the related US Core Data for Interoperability (USCDI) in a separate comment letter.

The [Alliance for Nursing Informatics](#) (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 5,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 3 million nurses in practice today.

The [American Nurses Association](#) (ANA) is the premier organization representing the interests of the nation's 3.6 million registered nurses. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA is at the forefront of improving the quality of health care for all.

As the reported most honest and ethical profession,¹ nurses play a significant role in advancing a robust ecosystem of health information exchange and make major contributions to improving our nation's

¹ Gallop Poll, December, 2017, "Nurses Keep Healthy Lead as Most Honest, Ethical Profession", retrieved from: <http://news.gallup.com/poll/224639/nurses-keep-healthy-lead-honest-ethical-profession.aspx>

population health.² We are well prepared to actively support the achievement of the 21st Century Cure's Act establishment of an interoperable health system that empowers individuals to use their Electronic Health Information (EHI) to the fullest extent; enables providers and communities to deliver smarter, safer and more efficient care; and promotes innovation at all levels throughout the ecosystem.

ANI and ANA fully support the expected outcomes identified in the Trusted Exchange Framework and Common Agreement (TEFCA):

- Providers can access health information about their patients, regardless of where the patient received care;
- Patients can access their health information electronically without any special effort;
- Providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals without having to access one record at a time (Population Level Data); and,
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability.

ANI and ANA Recommendations

We offer **four overarching recommendations** to ONC to promote the achievement of these outcomes. Our detailed rationale and specific recommendations to ONC follow.

1. Frame TEFCA implementation relative to its impact on improving individual and population health from a person-centered perspective.
2. Articulate clear roles for the Individual in partnership with the entire healthcare team in the health data exchange ecosystem.
3. Advance a **Do No Harm** focus to health information exchange throughout the health data-sharing ecosystem.
4. Include Nursing and Consumer representation in the TEFCA and USCDI FACA Workgroups.

1. ONC should frame TEFCA implementation relative to its impact on improving individual and population health from a person-centered perspective.

With the incremental approach ONC has designed to achieve **ALL** electronic health information being available and exchangeable for Individuals, QHINs and Participants, we encourage ONC to pay attention to the strong body of evidence that demonstrates successful adoption of new technologies hinges on development of solutions that are both easy to use/highly usable and

² Robert Wood Johnson Foundation (September, 2017) *Catalyst for Change: Harnessing the Power of Nurses to Build Population Health for the 21st Century*, retrieved from: <https://www.rwjf.org/content/dam/farm/reports/reports/2017/rwjf440286>

provide usefulness to its intended users.³ For consumer health information technology these two variables are the most reliable predictors of technology acceptance.⁴ Although the existence of patient portals for patients to access parts of their medical records has become widespread since the HITECH Act's CMS *Meaningful Use Incentive Program*, there is considerable evidence that these patient portals are vastly under-used⁵ and have poor usability.^{6,7} This is especially true for patients with limited health literacy.⁸

We strongly recommend:

a. Participatory Design to decrease the effort of accessing health information.

For TECCA to have its intended outcome of improved individual health, population health and decreased healthcare cost, individuals must be active participants, easily accessing and benefitting from the exchange ecosystem. To achieve optimum usefulness, a rigorous patient-centered participatory design is needed with a diverse sample.^{9,10} This focus on patient-centered usability of the information exchange software and usefulness of the information provided will ensure that TECCA access will align with patient-perceived information needs and will be highly usable.

b. Use of existing evidence of successful patient engagement in their health data

There is a considerable body of evidence related to patient engagement in their health data, an easily measureable variable within the EHR. Patients with strong engagement in their health data have better health outcomes.¹¹ It is important to recognize that this effect is largely dependent on health literacy.¹² Patient portals also provide limited data, not the entire record.

³ King, W.R. and He, J., 2006. A meta-analysis of the technology acceptance model. *Information & management*, 43(6), pp.740-755.

⁴ Holden, R.J. and Karsh, B.T., 2010. The technology acceptance model: its past and its future in health care. *Journal of biomedical informatics*, 43(1), pp.159-172.

⁵ Furukawa, M.F., King, J., Patel, V., Hsiao, C.J., Adler-Milstein, J. and Jha, A.K., 2014. Despite substantial progress in EHR adoption, health information exchange and patient engagement remain low in office settings. *Health Affairs*, 33(9), pp.1672-1679.

⁶ Goel, M.S., Brown, T.L., Williams, A., Cooper, A.J., Hasnain-Wynia, R. and Baker, D.W., 2011. Patient reported barriers to enrolling in a patient portal. *Journal of the American Medical Informatics Association*, 18(Supplement_1), pp.i8-i12.

⁷ Goldzweig, C.L., Orshansky, G., Paige, N.M., Towfigh, A.A., Haggstrom, D.A., Miale-Lye, I., Beroes, J.M. and Shekelle, P.G., 2013. Electronic patient portals: evidence on health outcomes, satisfaction, efficiency, and attitudes: a systematic review. *Annals of internal medicine*, 159(10), pp.677-687.

⁸ Sarkar, U., Karter, A.J., Liu, J.Y., Adler, N.E., Nguyen, R., Lopez, A. and Schillinger, D., 2010. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the Diabetes Study of Northern California (DISTANCE). *Journal of health communication*, 15(S2), pp.183-196.

⁹ Goel, M.S., Brown, T.L., Williams, A., Hasnain-Wynia, R., Thompson, J.A. and Baker, D.W., 2011. Disparities in enrollment and use of an electronic patient portal. *Journal of general internal medicine*, 26(10), pp.1112-1116.

¹⁰ Sarkar, U., Karter, A.J., Liu, J.Y., Adler, N.E., Nguyen, R., Lopez, A. and Schillinger, D., 2010. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the Diabetes Study of Northern California (DISTANCE). *Journal of health communication*, 15(S2), pp.183-196.

¹¹ Hibbard, J.H. and Greene, J., 2013. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health affairs*, 32(2), pp.207-214.

¹² Irizarry, T., Dabbs, A.D. and Curran, C.R., 2015. Patient portals and patient engagement: a state of the science review. *Journal of medical Internet research*, 17(6).

Efforts to engage patients in the data to be available via TEFCA must consider interventions (e.g., innovative display formats)¹³ for the varying health literacy, science literacy, and numeracy in the US population.

c. Rigorous testing and evaluation for interoperability and usability

We encourage formal testing for usability that aligns with industry standards for summative usability testing that are currently part of ONC's approach to EHR usability testing.¹⁴ We do note however, that many vendors have limited understanding or misconceptions of user centered design and usability testing¹⁵ and recommend strict enforcement of testing with a diverse group of patients before widespread release.

These evaluations should be conducted across a variety of clinical and provider organizations across diverse care settings, especially those with minimal resources (e.g. schools, mental health, public health, home health and long term care). This testing needs to evaluate mutual usability by Individuals, their authorized caregivers and clinical team members.

ANI and ANA members are a resource to support the development of use cases for pilot testing. We recognize future work will need more developed infrastructure to support spread and scale. We suggest leveraging the rigorous testing infrastructure of the [IHE North American Connectathon](#) as a potential resource and testing venue for this purpose.

d. Mutual Accountability for Person Centeredness (Advocacy/Education)

TEFCA empowers individuals and their authorized care givers with rights for health information access, exchange and use that are equal to the rights and responsibilities of those who have traditionally exchanged health information on behalf of individuals (providers, institutions, HIEs). Supporting individuals to exercise these rights represents a significant culture change for the US healthcare ecosystem and will require mutual accountability for person centeredness across all sectors.

Advocacy and education will be needed for individuals, families, care providers and all stakeholders across our institutions of care, including in diverse settings such as schools, long term care, home and community care. We recommend that these advocacy/education efforts (a) be a key activity for the new TEFCA FACA workgroup; (b) are framed to actively promote mutual accountability for person centeredness across the ecosystem; and, (c) are supported by well-developed education resources and scenario guidance that can be included in the ONC's HIT Playbook.

¹³ Garcia-Retamero, R., Okan, Y. and Cokely, E.T., 2012. Using visual aids to improve communication of risks about health: a review. *The Scientific World Journal*, 2012.

¹⁴ <http://www.healthcareusability.com/article/onc-meaningful-use-and-usability-testing>

¹⁵ Ratwani, R.M., Fairbanks, R.J., Hettinger, A.Z. and Benda, N.C., 2015. Electronic health record usability: analysis of the user-centered design processes of eleven electronic health record vendors. *Journal of the American Medical Informatics Association*, 22(6), pp.1179-1182.

e. Continued publishing of scenario-based guidance and FAQs by ONC and OCR

We encourage ONC and OCR to publish scenario-based guidance and FAQs directed to HINs, clinical providers and provider organizations, public health, community-based organizations, schools and individual consumers themselves. This guidance will support organizations to further develop education and advocacy resources that support the achievement of the four outcomes identified by the TEFCA.

There is limited understanding about the two distinct types of EHI exchange requests that involve an individual. One type involves an individual signing a HIPAA Authorization to legally allow a Covered Entity (CE) to share information with another CE. The other type of request involves an individual invoking their right of access under HIPAA and requesting a CE to share their information with a non-covered Entity (NCE) – which could be a third-party application, a community-based organization (CBO), or personal use access. Both of these requests (CE to CE, and CE to NCE) are separate and distinct ways in which the individual is engaged in the transfer of their health information.

The American Health information Management Association’s (AHIMA) recent release of a Standard Education Request for Information Form¹⁶ (July 2017) in paper format, builds on the Office for Civil Rights’ (OCR) interpretive guidance on an individual’s right of access under HIPAA (January 2016).¹⁷ While necessary, HIPAA’s guidance and AHIMA’s form are not sufficient to support the widespread education and guidance needed across a healthy exchange ecosystem. This end goal will need direct face-to-face engagement, advocacy and education, and nurses are ideally placed to give this support. Nurses will continue to be the front line of patient education across the US and nursing informatics professionals will be essential to designing effective clinical and patient workflow solutions.

2. ONC should articulate clear roles for the individual in partnership with the entire healthcare team within the health data exchange ecosystem.

The draft TEFCA has done a good job of defining the individual and their authorized caregiver. Throughout the draft though, it is unclear how “provider” is defined. This can cause considerable confusion and a focus on medically-generated data, rather than a more person-centered view of health data. Nurses, along with pharmacists, social workers, physical therapists and other clinicians serve across our nation in diverse settings to improve population and public health for individuals, family and communities. Therefore, we strongly recommend clear Inclusivity in language and data attribution to nurses and other care providers in inter-professional teams.

¹⁶ AHIMA, July 2017, “AHIMA Releases Standardized Patient Request for Information Form,” retrieved at: <http://journal.ahima.org/2017/07/20/ahima-releases-standardized-patient-request-for-information-form/>

¹⁷ HHS Office of Civil Rights, “Individuals’ Right under HIPAA to Access their Health Information 45 CFR § 164.524,”

We strongly recommend:

a. **ONC recognize the unique role of nurses in creating and exchanging health data**

Relevant to the TEFCA, ANA has previously stated in [comments on "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0,"](#) dated April 2, 2015:

“Registered nurses are pivotal in identifying patient-centered problems (e.g., incontinence, functional status) through standardized screening and assessments and compiling data. They provide information to other clinicians and are an essential source of information for patients, families and other caregivers. Registered nurses also have a critical role in documenting health information in current electronic health records (EHR) and providing care coordination in multiple roles, including during care transitions between units in acute care and across all care settings. Utilization of terminologies (and standards) that support nursing practice and patient-centered care will ensure that the steps articulated in this roadmap will result in data that informs comprehensive patient-centered care. Data collected by nurses and entered in the EHR ensures the capture of the contributions of registered nurses, the largest group of healthcare professionals. The promise of data analytics to improve patient care and outcomes will not be fully achieved without the inclusion of this data.”

b. **ONC should recognize the unique needs of School Nurses in schools and health centers**

One role that is not highlighted well in TEFCA is that of the school nurse. Their role should not be overlooked as today, we count 95,800 fulltime equivalents, or 132,300 school nurses in private and public schools;¹⁸ and 2315 School-Based Health Centers, in 2014. School nurses practice in elementary, middle and high school, often supporting many schools in a region or district. School Nurses provide healthcare in school-based clinics, including in colleges and universities. Advanced Practice Nurses also practice in these settings, including many Nurse Run Clinics. School Nurses exchange health data with individuals and their authorized caregivers on a routine basis, as well as with others in the community health system, especially notable in the pediatric community.

Of note, schools are the de facto enforcers of immunization statutes across the nation, but due to limited interoperability, access to most often “read only” data is not adequate. In Washington State, school nurses are piloting a successful program to use the IIS ([Immunization Information System](#)) to manage the entire process of collecting, analyzing and reporting immunization data. A school module¹⁹ aggregates data by school and allows the nurse to examine their school records. Reports are submitted automatically from the school module and the system represents a significant component in population health management and data

¹⁸ Willgerodt, M.A., Brock, D.M., and Maughan, E.D. “Public School Nursing Practice in the United States,” *The Journal of School Nursing*, January 17, 2018, Sage Journals, retrieved at: <http://journals.sagepub.com/doi/abs/10.1177/1059840517752456>

¹⁹ Washington Department of Health, WA Immunization Information System School Module
Retrieved at: <https://www.doh.wa.gov/CommunityandEnvironment/Schools/Immunization/SchoolModule>

resource. Licensed nurses can also enter provider verified data on immunizations received outside of WA.

c. A clear unique clinician identifier is needed for data attribution for all members of the healthcare team

We recommend that a unique clinician identifier be captured across care settings for data analytics that will better inform a learning health system, and strengthen partnership for individuals and their authorized caregivers -- and their health care team partners. ANA and ANI support the use of a unique clinician identifier, such as the National Provider Identifier (NPI) or the National Council of State Boards of Nursing (NCSBN) ID, be captured for all nurses and care team members. A unique clinician identifier will ensure data attribution to all care providers across the inter-professional team directly contributing to patient outcomes.

d. TEFCA will need to support new models of care including Nursing-Lead innovation

One such opportunity comes from The American Academy of Nursing (AAN) in their work to actively foster innovation in care delivery models through their **“The Raise the Voice: Edge Runner Initiative”** <http://www.aannet.org/initiatives/edge-runners>. Current initiatives include several models for considering the importance of health information exchange across the care continuum to inform population health. Examples include: care coordination models, such as the **“11th Street Family Health Services”** that is based on trans-disciplinary care teams and community partnerships; the **“Aging in Place”** model which applies registered nurse care coordination and health promotion to support high quality services in the home; and additionally, telehealth initiatives like the **“Complex Care Center”** model which links providers through evidence-based and innovative solutions.

The Complex Care Center model demonstrates the need and challenges for cross continuum health information exchange over an extended period of time for high frequency and complex care patients.²⁰ This innovative nursing model of care coordination operates as a change agent and facilitator for changing the system, rather than trying to change the patient.²⁰ The Complex Care Center’s model is inherently interdisciplinary and creates collaboration across systems and disciplines, and includes: 1) a 10 year analysis of the medical record to capture the full patient story and identify root causes of frequency/complexity; 2) conferences for care management providers across the continuum of care (regardless of health system affiliation); 3) a shared evidence-based plan (Complex Care Map) to change system response; 4) embedding the plan in the medical record; 5) following the patient on every admission; and, 6) readdressing the plan in iterations. Once referred, patients are followed for life and the Center re-engages the process as needed on every subsequent admission and emergency department visit. Reported outcomes for 661 Complex Care Center patients over a 12-month period from initial intervention

²⁰ American Academy of Nursing, Edge Runner Initiatives, retrieved at: <http://www.aannet.org/initiatives/edge-runners/profiles/edge-runners--complex-care-center>

demonstrated a 34% reduction in inpatient observation/admissions; a 26 % decrease in length of stay; and a 35 % decrease in ED/urgent care visits.²¹

Each of the AAN Edge Runner programs have demonstrated an improvement in patient outcomes and progress toward fundamental transformation in enabling our healthcare system to deliver the best possible care at an acceptable cost – moving American healthcare away from its current hospital-based, acuity-oriented, physician-dependent paradigm toward a patient-centered, convenient, helpful and affordable system.

3. ONC should advance a Do No Harm focus to health information exchange throughout the health data-sharing ecosystem.

We strongly recommend:

a. Patient Matching to Ensure Privacy, Security and Safety

A critical priority for patient safety and the seamless exchange of trusted data is patient matching. According to the online article, [ECRI: Patient Identification errors common, potentially fatal, the report](#), [ECRI Institute PSO Deep Dive: Patient Identification](#), identified,

“Wrong-patient” errors are not uncommon and such mistakes may have deadly consequence, according to a new report. Researchers from ECRI Institute, a nonprofit group focused on patient safety, examined more than 7,600 cases of wrong patient errors recorded between January 2013 and June 2015 at more than 181 facilities. They concluded that these instances, which were reported voluntarily without fear of malpractice repercussions, represent just a small portion of such errors. More than 90 percent of the mistakes were detected before patient harm occurred, according to the [report](#), but two were fatal and others may have had similar consequences had they not been caught²².

ANA has advocated for a unique, voluntary patient identifier to enhance privacy and data matching, but what is of utmost importance is that all stakeholders, including the healthcare consumer, are included in the dialogue and processes associated with ensuring privacy, security, and patient safety are sustained.

b. Minimize potential for exacerbation of Health Disparities

Data collected should never used to discriminate in care delivery, reimbursement or be used to create government policies that would exacerbate health disparities.

ANI and ANA affirm that the development and management of HIT standards as a public good, operated in a nonprofit, non-proprietary basis, continue to advance with low barriers for

²¹ Hardin, L., Kilian, A., Muller, L., Callisan, K., Olgren, M. “Cross-Continuum Tool Is Associated with Reduced Utilization and Cost for Frequent High-Need Users,” *Western Journal of Emergency Medicine*, Volume XVIII, no. 2: February 2017, (189-200).

²² Minemyer, P., “[ECRI: Patient Identification errors common, potentially fatal, the report](#),” *Fierce Healthcare*, retrieved at <https://www.fiercehealthcare.com/healthcare/patient-identification-errors-a-common-and-potentially-fatal-issue>.

participants and end-users across the care continuum to review, reference, or use. We express concern about the timing of inclusion of Social Determinants of Health as a data class (in the USCDI) and encourage an acceleration of defining these data classes, and managing the complexities of widespread adoption for the benefit of our nation's health.

We express concern about TEFCAs consideration for a single Recognized Coordinating Entity (RCE), and its capacity to support the diverse needs of communities across our nation, especially those which are rural and under-resourced, and also those where technology adoption is still immature and under-resourced, e.g. public health, long term care, behavioral health and community organizations.

We express concern about adding cost for individuals and the health care ecosystem. We support further work in empowering consumers and health policy to support Consumer Directed Exchange (CDEX), consistent with our engagement with the CARIN Alliance.²³ We anticipate that there may be many hidden and additive costs for capabilities such as broadcast queries, which will not be efficient for consumers desiring to have access to all their data, in one place, and when they need it.

We express concern about the voluntary nature of TEFCAs. If we as a nation are not "all in", will this limit shareable comparable data for care and research?

c. Minimize workflow disruption to clinicians

We urge ONC to ensure more comprehensive interoperability while minimizing additional user workload and workflow disruption. Despite the multiple positive effects of electronic health data and electronic health records, there are also substantial unintended consequences, which have increased workload and not led to needed interventions or policy changes. Additional workload and changes to workflow can adversely impact patient safety.²⁴ It is critical that TEFCAs not further increase the burden of EHR and HIE use beyond what exists today. Our concern about workflow disruptions is consistent with the recommendations put forth by nationally recognized nurse leaders^{25,26} and the American College of Physicians in their recommendations to mitigate the negative impact of administrative burden on physicians their patients and the healthcare system as a whole.²⁷

²³ CARIN Alliance, <http://carinalliance.com/what-we-do/>

²⁴ Fairbanks, R.J. and Caplan, S., 2004. Poor interface design and lack of usability testing facilitate medical error. *The Joint Commission Journal on Quality and Safety*, 30(10), pp.579-584.

²⁵ O'Brien A, Weaver C, Settergren T.T., Hook M.L., Ivory C.H., 2015. EHR documentation: the hype and the hope for improving nursing satisfaction and quality outcomes. *Nursing Administration Quarterly*. 39(4), pp. 333-339.

²⁶ Staggers, N., Elias, B.L., Hunt, J.R., Makar, E. and Alexander, G.L., 2015. Nursing-Centric Technology and Usability A Call to Action. *CIN: Computers, Informatics, Nursing*, 33(8), pp.325-332.

²⁷ Erickson, S.M., Rockwern, B., Koltov, M. and McLean, R.M., 2017. Putting patients first by reducing administrative tasks in health care: a position paper of the American College of Physicians. *Annals of internal medicine*, 166(9), pp.659-661.

4. **ONC should include Nursing and Consumer representation in the TEFCA and USCDI FACA Workgroups.**

ANI and ANA will provide letters of support for nursing informatics experts to serve in these roles. ONC should also select consumer advocates to serve.

Part A: Feasibility of Principles for Trusted Exchange	
Principles	ANI and ANA Comments & Recommendations
<p>1: Standardization <i>Adhere to industry and federally recognized standards, policies, best practices and procedures.</i></p>	<p>We recommend that ONC ensure alignment between the policies of the TEFCA and the standards referenced in Interoperability Standards Advisory (ISA)²⁸ recognizing that TEFCA and ISA should be mutually reinforcing documents. ANA and ANI have continued to provide annual feedback to standards for nursing assessment, intervention and evaluation through the ISA feedback process.</p> <p>We strongly recommended clear inclusivity in language and data attribution to nurses and other care providers in inter-professional teams.</p>
<p>2. Transparency <i>Conduct all exchange openly and transparently.</i></p>	<p>Transparency is a mutual accountability for all exchange partners in the ecosystem.</p> <p>We strongly recommended clear inclusivity in language and data attribution to nurses and other care providers in inter-professional teams.</p> <p>Advocacy/Education, Scenario Based Guidance will be necessary for broad clinical and patient education roles, including understanding the distinctions for exchange for Individual Right of Access with of Covered Entities and Non-Covered Entities (see our comments page 4-5)</p>
<p>3. Cooperation and Non-Discrimination <i>Collaborate with stakeholders across the continuum of care to exchange Electronic Health Information (EHI), even when a stakeholder may be a business competitor</i></p>	<p>Patient consent that encourages understanding of the use and reuse of their health data is needed; including assuring patients understand the use of their health data for population health improvement efforts.</p> <p>See our Recommendation ONC should Advance a <i>Do No Harm</i> focus to health information exchange throughout the health data-sharing ecosystem (page 8-10) b. Minimize potential for exacerbation of Health Disparities</p>
<p>4. Privacy, Security and Patient Safety <i>Exchange EHI securely and in a manner that promotes patient safety and ensures data integrity</i></p>	<p>See our Recommendation ONC should Advance a <i>Do No Harm</i> focus to health information exchange throughout the health data-sharing ecosystem (page 8-10) a. Patient Matching to Ensure Privacy, Security and Safety</p>

²⁸ <https://www.amia.org/sites/default/files/AMIA-Comments-on-Trust-Framework-RFC.pdf>

Part A: Feasibility of Principles for Trusted Exchange

Principles	ANI and ANA Comments & Recommendations
<p>5. Access <i>Ensure that individuals and their authorized caregivers have easy access to their EHI</i></p>	<p>See our Recommendation ONC should frame TEFCA implementation relative to its impact on improving individual and population health from a person-centered perspective.(page 2-5) c. Mutual Accountability for Person Centeredness (Advocacy/Education)</p>
<p>6. Data-driven accountability <i>Exchange multiple records for a cohort of patients at one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.</i></p>	<p>Nurses and members of the care team will have need for access, use and re-use of health data.</p> <p>We strongly recommended clear inclusivity in language and data attribution to nurses and other care providers in inter-professional teams.</p> <p>See our Recommendation ONC should articulate clear roles for the Individual in partnership with the entire healthcare team in the health data exchange ecosystem (page 5-6)</p>

Part B: Minimum Required Terms and Conditions

Clarity of Language	ANI and ANA Comments & Recommendations
<p>1. Definitions</p>	<p>ANI/ANA recommend provider-inclusion language to describe collaborative care across healthcare providers that includes Advanced Practice Registered Nurses and other specialty nurses such as, School Nurses and other disciplines (e.g. Pharmacists, Social Workers, and Physical Therapists) that provide care in diverse settings, beyond the physician.”</p> <p>We strongly recommended clear inclusivity in language and data attribution to nurses and other care providers in inter-professional teams.</p>
<p>2. Requirements of Qualified HINS</p>	<p>We support the ONC language as written.</p>
<p>3. Standardization</p>	
<p>4. Transparency</p>	
<p>5. Cooperation and Non-Discrimination</p>	
<p>6. Privacy, Security and Patient Safety</p>	
<p>7. Access</p>	

Part B: Minimum Required Terms and Conditions

Clarity of Language	ANI and ANA Comments & Recommendations
8. Data-driven Choice	
9. Participant Obligations	
10. End User Obligations	

Additional Questions

Questions	ANI and ANA Comments & Recommendations
Are there particular eligibility requirements for the Recognized Coordinating Entity (RCE) that ONC should consider when developing the Cooperative Agreement?	<p>We express concern about TEFCAs consideration for a single RCE, and its capacity to support the diverse needs of communities across our nation, especially those which are rural and under-resourced, and also those where technology adoption is still immature, e.g. public health, long term care, behavioral health and community organizations.</p> <p>We recommend that ONC include patient/consumer representation in the advisory group that develops criteria and selects the RCEs</p> <p>We recommend that ONC include nurses and other clinicians representative of the broad continuum of care, in the advisory group that develops criteria and selects the RCEs</p>
Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?	<p>See our Recommendation</p> <p>2.c. A clear unique clinician identifier is needed for data attribution for all members of the healthcare team (page 6)</p>

Additional Questions

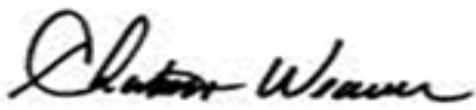
Questions	ANI and ANA Comments & Recommendations
<p>Advancing Interstate Exchange and Data Completeness for EHI Data residing outside of EHR and Pharmacy systems</p> <p>Use Case: State Prescription Drug Monitoring and the Opioid Epidemic</p>	<p>ANA is participating in the National Quality Forum’s, National Quality Partners™ Opioid Stewardship Action Team, which is a six-month intensive project, with the final product being a “playbook” which will be released and publicly available in March 2018. The charge for this team is to “identify strategies and tactics to help physicians, clinicians, and other prescribers better manage patients’ pain while reducing the risk of opioid addiction²⁹.”</p> <p>ANA and ANI encourage ONC to collaborate with this group of experts and leverage the pending publication to be released in March to inform the TEFCA.</p> <p>We have concern about differences in supporting participants across state lines, which have differing “applicable laws” for use and disclosure of EHI and for which different kinds of consent are required for different kinds of conditions.³⁰</p>
<p>How could a single “on ramp” to data that works regardless of a chosen HIN support broader uses for access and exchange of prescriptions for controlled substances contained in PDMPs</p>	<p>Currently, there is not complete interoperability among the states on data sharing. In addition, current epidemiological data are not collected as part of PDMPs. A single onramp to such data could not only bolster prescription drug monitoring but open avenues to more comprehensive data mining to support population health and evidence-based practice development.</p>
<p>How could a TEFCA involved approach for supporting opioid use cases distinguish between technical capabilities versus applicable organizational, local, state, and/or federal requirements for PDMPs?</p>	<p>Given the variation of state laws governing PDMP use and data, should interstate connectivity for PDMP data be enabled via a TEFCA use case to address the national opioid epidemic? A series of related use cases could be made to use TEFCA as a test bed for addressing the opioid crisis.</p> <p>Consider SAMHSA or IHI/NPSF. Nursing experts are included in these groups</p>

²⁹ National Quality Forum, National Quality Partnership™ Opioid Stewardship Action Team, retrieved at https://www.qualityforum.org/National_Quality_Partners_Opioid_Stewardship_Action_Team.aspx.

³⁰ Wicklund, E. (February 6, 2018) m-Health Intelligence “Senators Want Telemedicine Up Front In The Opioid Epidemic Battle” Three senators are asking the DEA to enable healthcare providers to use telemedicine more freely to launch and expand addiction treatment programs. Retrieved at: <https://mhealthintelligence.com/news/senators-want-telemedicine-up-front-in-the-opioid-epidemic-battle>

ANI and ANA, commend the work ONC is leading to enable access and exchange of health information across our country for Individuals and their authorized caregivers in partnership with the entire healthcare team in the health data exchange ecosystem. We look forward to ongoing contributions to make a fundamental difference in improving individual and population health for our nation's citizens.


We thank you for the opportunity to provide comments.
Sincerely,



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