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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
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Floor 7
Washington, DC 20201

Submitted electronically at: exchangeframework@hhs.gov

Attention: Minnesota e-Health Initiative Statewide Coordinated Response to the Draft Trusted Exchange Framework

The Office of the National Coordinator for Health Information Technology:

Thank you for the opportunity to provide a response to the Draft Trusted Exchange Framework and Common Agreement. The Minnesota e-Health Initiative is pleased to submit comments on the Draft Trusted Exchange Network. We appreciate the work done to date by ONC to advance e-health to improve individual and population health.

Should you have questions you may contact:

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Sincerely,

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The Minnesota e-Health Initiative Statewide Coordinated Response to the ONC Draft Trusted Exchange Framework

Minnesota e-Health Initiative and Advisory Committee

The Minnesota e-Health Initiative vision is that all communities and individuals benefit from and are empowered by information and technology which advances health equity and supports health and wellbeing.

For the past fourteen years the Minnesota e-Health Initiative, led by the Minnesota e-Health Initiative Advisory Committee and the Minnesota Department of Health's Office of Health Information Technology (MDH-OHIT), has encouraged and supported e-health across the continuum of care. As a result, Minnesota is a national leader in e-health implementation and collaboration.

e-Health Advisory Committee

The Minnesota e-Health Advisory Committee is a 25-member legislatively authorized committee appointed by the Commissioner of Health to build consensus on important e-health issues and advise on policy and common action needed to advance the Minnesota e-Health vision. The Committee is comprised of a diverse set of key Minnesota stakeholders, including: consumers, providers, payers, public health professionals, vendors, experts in health information technology, and researchers, among others. The committee co-chairs are Alan Abramson, Senior Vice President, IS&T and Chief Information Officer, HealthPartners and Bobbie McAdam, Vice President, Information Technology, Medica.

Workgroups

Committee members participate in workgroups to address detailed topics such as privacy and security, health information exchange, and standards and interoperability. The workgroups are the primary vehicle for receiving public input and investigating specific e-health topics through discussion and consensus building. The workgroup co-chairs and participants contribute subject matter expertise in discussions, research, and analyses through hundreds of hours of volunteer time. MDH-OHIT staff facilitate, analyze and interpret data, and summarize findings that help support e-health policy development.

Statewide Coordinated Response Approach

This Minnesota e-Health statewide coordinated response to the request for public comment invited input from multiple stakeholders, including the Advisory Committee and workgroups. Representatives from Minnesota health and health care providers and health care systems

were encouraged to submit written comments and/or participate in two conference calls hosted by the Health Information Exchange and Privacy and Security Workgroups. Comments were collected, summarized and reviewed. The Minnesota e-Health Initiative recognizes the value in providing a statewide response to the Draft Trusted Exchange Framework.

The Minnesota e-Health Initiative also recognizes the value and need for individuals to be at the center of their care, where providers have the ability to securely access and use health information from different sources. We support actions to assure there is a system where an individual's health information is not limited to what is stored in electronic health records, but includes information from many different sources and provides a longitudinal picture of their health.

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Overall Comments on the Draft Trusted Exchange Framework

The Minnesota e-Health Initiative applauds the ONC efforts to improve and increase access and interoperability to support patient care and population health.

Minnesota, and every other state, has invested time, money and significant effort to expand the use of health information exchange to further the flow of data. As such, Minnesota is encouraged to see recognition of the multiple opportunities to improve data sharing and proposed resolutions that reflect guiding principles such as: standardization, transparency, cooperation and non-discrimination, privacy, security and patient safety, access, and data-driven accountability. However, because of the investments made, the Trusted Exchange Framework design must build on those investments, not only those made by states, but those of providers, payers, and health information exchanges (HIEs).

Minnesota is supportive of this direction toward a "network of networks" as this approach aligns with a recent Minnesota HIE Study and its recommendations For more information on Minnesota's current direction for HIE after an extensive study, see the Minnesota HIE Study Report, anticipated late February publication, at http://www.health.state.mn.us/e-health/hie/study/index.html.

While supportive of the overall direction of the Draft Trusted Exchange Framework, there were areas identified that could benefit from more clarity, additional actions or modification. Minnesota comments are organized by sections of the Draft Trusted Exchange Framework and highlighted below. Minnesota welcomes the opportunity for further input and involvement as the TEFCA unfolds.

Overall Comments and requests for clarification:

1) How will TEFCA align with other national efforts encouraging interoperability between HIE networks. For example, how does the TEFCA align with patient centered data home (PCDH) and the Strategic Health Information Exchange Collaborative (SHIEC)?

2) This effort requires significant patient matching acumen. How might the ONC help encourage use of similar methodology as to ensure high rates of patient matching accuracy?

3) It is unclear what, if any, centralized services might be available for Qualified HINs, such as a provider directory service, patient matching service, or other. If no centralized services will be available, will there be an expectation for Qualified HINs and HINs to follow particular standards for services that are shared (such as a provider directory or patient directory).

4) The framework seems more focused on supporting provider-to-provider exchange of information (using query and response capabilities) for individual patient care. It is unclear how PDMPs or other essential registry data sources (such as public health registries) will fit into this framework. How will this model incorporate the essential registry data sources? This will be important in order to achieve the identified permitted uses such as for public health and achieving the goals of population health.

5) What will be the process for identifying, reaching consensus if necessary, and implementing new and emerging use cases? The process should be open and transparent with input

provided by a wide range of stakeholders.

6) It appears throughout the document that the information to be shared is not likely to be discrete, consolidated information, which is critical to making information more useable in support of population health. Similar to expanding for new use cases, it would be helpful for ONC to describe the path towards being able to retrieve discrete, consolidated information from the Qualified HINs/HINs.

7) It is unclear why the definition of HIN allows for an "individual" to meet the requirements. It would be helpful for ONC to describe an example where an individual would likely fill the role of a HIN.

8) Minnesota recommends that ONC consider the following:

   a. provide more specific examples of what type of organizations and characteristics of those organizations are envisioned to will be a HIN or a Qualified HIN

   b. clearly articulate the advantages and requirements of being a Qualified HIN, HIN, or participant

   c. to meet the requirements of any of these levels will federal funding available?

9) Several concerns and needed clarifications are identified on behalf of public health (specifically related to immunization registries). Minnesota encourages review of national public health comments such as those from the American Immunization Registry Association (AIRA). Minnesota-specific comments include:

   a. The TEFCA as it stands doesn't meet public health needs. It doesn't set the expectation that "pushing" data is something that needs to be done (it also doesn't disallow it). In many cases public health is not the creator of data and isn't aware that there is new data to query for it. It is vital that data is "pushed" to public health as it is generated in order for us to do our work effectively. Due to this, if there is not an expectation that "push" messages are available then existing public health interfaces would need to remain in place and future "push" interfaces would have to be built, diluting the "One On Ramp" concept that the TEFCA presents.

   b. The TEFCA references a 12-month timeline for implementing new standards in several places. Given the way that public health is funded and operates that would not provide enough time for public health agencies to implement a new standard. Not only would funding need to be secured, but potentially there would be a need for new or updated legislation to allow the change or expansion of use of the data. Similarly, health systems tell us it can take 15 – 20 months to implement some EHR updates across the large health system.

   c. Patient consent is important to consider and respect in data sharing, however, some public health reporting is legally required regardless of a patients indication to share it or not. Some public health data is highly sensitive and may not be appropriate to share with all providers (unless explicitly indicated by the patient). Sharing of data and patient consent indicators needs to be carefully considered and implemented so that only appropriate parties have access to data. A TEFCA plan and roadmap should have explicit components regarding privacy, consent, and security.

   d. Some data (e.g., immunization histories) would potentially exist in several different locations. A patient may live on the border of two state registries and receive care from

several providers that span jurisdictions. If all parties were participating and a broadcast query went out you could potentially have multiple registries and multiple providers responding back the same piece of data with minor variations. It will be critical that when the Qualified HIN consolidates this to send it back to the originator of the query that the correct version of each piece of data is included. The Qualified HIN information and service architecture should account for record consolidation and deduplication.

e. The broadcast query sending first, a messages asking if anyone has data, and then a second messages asking for the data they have, seems to create an unnecessary amount of message traffic. Allowing receivers to either indicate they do not have any data or to send the data they have on the first ask seems much more efficient. The models proposed should be tested and evaluated for optimization.

f. The TEFCA should allow for use of existing CDC/ONC required standards and technologies that have had significant amounts of resources involved in implementing to date. HL7 V2 messages and the CDC SOAP WSDL being the two that impact immunization registries the most. A plan for measuring use of existing standards should be established and a pathway provided for updating standards going forward.

Part A- Principles for Trusted Exchange

Principle 1 - Standardization:

Adhere to industry and federally recognized standards, policies, best practices, and procedures.

The need for standardization is critical to allow for the easy flow of information across the entire country. However, the language in this section is quite broad and refers to interoperability in general terms.

Minnesota would recommend that ONC take a closer look at how the relationship between principles and current standards is reflected; directly linking the principles in Part A with the requirements in Part B would be a useful first step.

Minnesota would also recommend a stronger connection to the US Core Data for Interoperability (USCDI), calling it out specifically, to emphasize the importance of exchanging all the version 1 recommended data elements. Including the implementation guidance as well as best practices for using the shared information.

Comments and requests for clarification:
1) How will standards changes be decided and incorporated?
2) Who will decide which standards are accepted?
3) How many versions, if more than one, will be accepted at any given time?
4) What would be the implementation time period?
5) One year is stipulated in some cases which may not be enough time for many organizations to implement.

Principle 2 - Transparency:

Conduct all exchange openly and transparently.

While Minnesota agrees with and supports the overall concept of transparency outlined in the requirements for publically available agreements, for participant agreements using and disclosing ePHI, and for privacy practices for HINs and Qualified HINs more detailed descriptions on how this would work are needed to move forward with the principle conceptualized here.

Comments and requests for clarification:

1) What does agreeing to all the permitted purposes mean for Minnesota, which has consent requirements that are more protective than HIPAA?

2) What would the RCE role be in the management or oversight of this principle for HINs and Qualified HINs?

3) Is there consideration of including cost transparency in that process as well? Would such transparency be the same as having one price structure? If pricing is transparent, does that mean everyone is receiving the same pricing or not?

Principle 3 - Cooperation and Non-Discrimination:

Collaborate with stakeholders across the continuum of care to exchange Electronic Health Information, even when a stakeholder may be a business competitor.

Comments and requests for clarification:

1) Will there be any enforcement policies if participation is voluntary? If so, what might those enforcement policies entail? What is the role of the ONC, RCE, Qualified HINs, HINs, and states in enforcement?

2) Since an EHR is not required to connect to other HINs, what requirement would be developed (e.g., through EHR certification) to require EHRs to share that information with other HINs?

3) Is there a mechanism for stakeholders to report misconduct? Example 1: someone has applied for access to a Qualified HIN and they are not able to participate or given access? Example 2: The RCE is the governance body and has an agreement with a QHIN to meet the principles, but a vendor feels Qualified HIN is being discriminatory, how does the vendor report to RCE for compliance and monitoring? This assumes they will have some authority for compliance and monitoring compliance.

4) It would be helpful to have more clarification on "not using privacy laws" as a reason for not sending information.

5) Is ONC expecting that the health care technology industry will take ownership of this framework and the federal government role, if any role, will become more limited?

6) What does ONC envision that the audit requirements for use and sharing of health information might look like? Any audit should have a standard set of data using a standard format and process.

Principle 4 – Privacy, Security, and Patient Safety:

Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity.

Comments and requests for clarification:

1) Principle 4 would benefit from some parsing and better alignment. The distinctions and overlaps among privacy, security and patient safety could benefit from making requirements more concise and clear. This principle may be mixing several concepts such as privacy and security that may not connect well with patient safety. Following HIPAA could be considered such as: ensure patient confidentially by defining effective privacy policies and implementing strong security. Patient safety is a distinct concept and should be separated out.

2) A broad set of permitted purposes are included. It is unclear how the framework will be implemented when different states have different laws either enabling or prohibiting HIE for particular permitted purposes? How will a Qualified HIN or HIN know what data is allowed, for what purposes and how inappropriate secondary uses of data will be avoided? It appears that HINs are allowed to retain information that they query – if so, Minnesota recommends that ONC clearly articulate under what circumstances keeping PHI is either required, allowed, or prohibited. In addition, it will be important to understand how varying state laws will interact with the agreed upon policy.

3) Are individual providers, HINs, Qualified HINs or all responsible for quality audits? Are there going to be quality standards that must be met? While there is widespread support for sharing information; using the information to the full extent requires that it be high quality.

4) Patient Matching is often not accurate. Since there is no option for a National Patient Identifier, will the ONC consider using Blockchain software to improve the patient matching capabilities across the QHINs?

Principle 5 - Access:

Ensure that Individuals and their authorized caregivers have easy access to their Electronic Health Information.

Comments and requests for clarification:

1) Could ONC provide a more concise definition of authorized caregivers? Would there be additional criteria to grant or revoke a caregiver's access by an individual? Minnesota recommends a core set of criteria like licensure or certification and additional role based or profession-based criteria be allowed by state.

2) Will ONC be providing any guidance on how patients and caregivers will be offered access to their electronic health information (e.g., participant, EHR portal, HIN or perhaps even the Qualified HIN)? O-Or, will individual access be set up at the discretion of the HIN or Qualified HIN? Will the vendor for this individual access to the framework be required to include capability of consolidating the individuals' records for usability?

3) What would ONC consider examples of "unnecessary barriers" (page 19)?

4) Would there be a common process for patients/individuals/caregivers if they find an error in a record and need a method to communicate and have it corrected? Would that communication start with the individual provider, HIN or Qualified HIN level?
5) There should be clarification on the role and expectation of the individual and caregivers, providers, HINs, and QHINs. (Not only in this principle but all of the principles.). Does it mean that all Qualified HINs have to provide ability for patient to access or to provide the information? We suggest that a minimum establish and a standard set of advanced functions.
6) Does this principle imply giving or allowing access? Or both? Does this include having a portal for individuals? Or not limiting requests from patients?
7) What liability protections would be in place for providers sharing clinical notes?

Principle 6 - Data-driven Accountability:

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.

Comments and requests for clarification:
1) These cohort and population level requests may be particularly helpful and beneficial from an ACO perspective and useful in providing care for groups of individuals. The potential benefits are to have cost savings; experience reduced number of errors; eliminate the need to pull data from different entities; and not having to buy expensive software.
2) Minnesota supports this concept as our state has significant provider participation in both Medicare and Minnesota Medicaid ACOs. However, there are concerns about the capabilities and capacities of the industry to complete this. There is work happening on the standards for the size of data that would be involved. Minnesota recommends that ONC take a cautious, metered approach, because this will take a lot of time, money, and effort to complete. Minnesota believes this will take more time than currently outlined.
3) The proposed approach seems more reasonable if you know what you are querying for. Some individuals expressed concerns with terms like "broadcast query". This will be too large of a burden on HIE networks, especially larger national HIE networks. ONC should provide more information on the use cases for implementing a broadcast query and information on implementation requirements.
4) Public health should be added as an actor to this principle. All of those activities are what public health at the local, state, and federal do and why they need access to information.

PART B- Minimum Required Terms and Conditions for Trusted Exchange

Section 1 Definitions	Overall Concept or Excerpt	Comments and request for clarification
Overall	*Many definitions are referenced as the HIPAA definition or rule*	How will sharing of information between two entities, for example across different states with different privacy and security laws be accomplished?
Breach (page 23)	*Has the meaning assigned to it in 45 C.F.R.§164.402 of the HIPAA rules*	ONC is defining as under HIPAA, however every state also has its own state statutes on breach as well. Could ONC please clarify which definition is primary or exclusive?
HIN (page 26)		Under the definition of HIN, it would be helpful to further define what the term "unaffiliated" means. For example, if two organizations are partners in an ACO but have different ownership, would they be considered affiliated?
Permitted Purposes (page 28)	*Payment, Health Care Operations, Public Health, Individual Access, and Benefits Determination as permitted and pursuant to an Authorization and to the extent permitted under Applicable Law.*	1. Is it permitted purposes under applicable law? State or Federal law? Should it be federal and Minnesota/state law? Is it possible to address both state and federal law? 2. Is this a finite list or is ONC anticipating expanding this list? 3. If this is per Minnesota law, this may require a number of consents. Another option is for all trusted members to obtain consent at the provider level, share the consent level by provider, and then share information for only those providers for whom the individual consented to share. 4. Is it anticipated that ONC would move to more granular consent? If so, what type of granularity and is it feasible both technically and process wise? 5. Would Qualified HINs/HINs be required to have the ability to manage the data flow with granularity? 6. Will the RCE be helping to define these processes? 7. Will the party who is disclosing information to Qualified HIN (HIN or HIN to provider) be

Section 1 Definitions	Overall Concept or Excerpt	Comments and request for clarification
		responsible for obtaining consent? Will there be parameters on the consent such as purpose, data, and recipients. Alternatively, will the consent be an all or nothing? 8. Would it be up to the patient to identify special categories or providers? Is consent by categories feasible technically and process wise? 9. What is the capability and capacity for highly granular consent? 10. Would there be a standard process for revocation of consent?
Qualified HIN (page 28)		The definition of participant neutral is not entirely clear. What does it mean to be participant neutral?

Section 2 - Requirements of Qualified HINs

Comments and requests for clarification:
1) Is there an expectation that HINs and Qualified HINs have the ability to manage the flow of data with consent with a fair amount of granularity with respect to what patients want to share? If not, is there concern that more individuals would just opt-out entirely?
2) How would Minnesota and other state specific consent and data-sharing laws be addressed in the framework and common agreement?
3) How will TEFCA manage all the permutations of consent; with 50 standards around consent management, a common agreement will be difficult to navigate. Is it possible to have one standard?
4) Is it the responsibility of the Qualified HIN to have consents? See section 6.1.6 (and comments in privacy, security and patient safety). Currently HIEs manage consent from multiple providers in Minnesota. Could this responsibility be kept at that local level and utilize the Qualified HIN only as a transport conduit to reach other Qualified HINs?

Section 3 – Standardization

Comments and requests for clarification:
1) Minnesota is concerned about the timeline and technical feasibility for broadcast and population health query. Minnesota would recommend ONC have standards in place before beginning to implement.
2) Minnesota recommends that ONC evaluate a standard consent management process e.g., SAMSHA Consent-2-Share. A common standard for opt-out would be a good place to start. In Minnesota all providers obtain the consent and share the consent flag with

the HIO. This method meets the SAMSHA requirements, so all providers the individual consents to shares the information. This is unlike most of the National Initiatives, which currently filter out all behavioral health/chemical dependency providers' information – even when the individual has consented (and expects) to have their behavioral health information shared.

Section 4 – Transparency

No specific comments on requirements were identified - see comments for Principle 2.

Section 5 - Cooperation and Non-Discrimination

Comments and requests for clarification:

1) It would be helpful for ONC to clarify the following: in the agreement on page 36 (under 5.3.1), the provision that allows charges to be made between Qualified HINs may be in conflict with some state laws. For example, in Minnesota, state law prohibits HIE entities from charging one another for exchange of meaningful use transactions.

Section 6 - Privacy, Security, and Patient Safety

Comments and requests for clarification:

1) The section 6.1.1. Individual access. Minnesota needs to have a clear understanding who has access. Who has the responsibility to "…ensure providers and organizations participating in exchange have confidence that appropriate consent…"? Does there needs to be confidence in the process? Confidence in the Qualified HINs? Also, if consent is not sent correctly from a provider, who is held responsible. Would these questions be addressed in the agreement for Qualified HINs?
2) Does ONC envision that both HINs and Qualified HINs have patient facing technology?
3) What are the services a Qualified HIN might offer? Is the Qualified HIN just a "go-between" for HINs or are there services that they provide (e.g., links to national directories). Minnesota suggests using the Framework to build on investments already made in HIE - encouraging HINs to continue and expand established services for individuals, providers, communities and payers, and the Qualified HINs to provide the nationwide access to information (query/response and push to the Patient Centered Data Home) when that information is not already contained in the HIN.
4) Minnesota recommends a standard electronic approach for consent management and that ONC evaluate tools such as the SAMSHA Consent-2-Share.

Section 7 - Access

Comments and requests for clarification:

1) If an individual requests for no exchange at one provider location (opt-out) and that is submitted by provider to HIN is it clear whether the patient is requesting a complete opt-out (all providers) or just for the provider submitting the opt-out request (if there

even is that level of granularity)?

2) In the agreement on page 43 (under 7.2), it would be helpful to understand what the definition of "exchanged" is meant to include. For example, can a HIN store information, but not query for that information if a person has opted out? Fully excluding the information could be problematic if a person eventually opts back in.

Section 8 - Data-driven Choice

Comment and requests for clarifications:

1) Minnesota would like a more precise definition of population level data. We recommend the perspective be both a cohort population health and of a geographical such as state, county.

Section 9 - Participant Obligations

No comments

Section 10 – End User Obligations

No comments

US Core Data for Interoperability

Version 1: Data Classes

- Common Clinical Data Set (CCDA)
- Provenance
- Clinical Notes

Minnesota supports the use of the common clinical data set (requirement under 2015 EHR certification) with the very useful addition of clinical notes and provenance. The inclusion of clinical notes and provenance will greatly enhance the interpretation of other data elements and provenance will increase the confidence/trust other providers will have for the information.

There remains wide variation in the CCDs that the various EHRs can create/send. How will ONC (or HINs/Qualified HIN) assure that the quality of CCDs is as consistent as possible?

There is accommodation for providers that do not have a complete data set (required to send only what they have or what their EHR can generate); however, might ONC offer incentives to encourage smaller clinics to work towards a more complete data set?

Dentists in Minnesota already use many EHRs, but they are not certified. Minnesota dentists may not be capable of exchanging the proposed USCDI set and our practitioners will be behind. Minnesota recommends that ONC consider including dental information and dental capabilities. e.g., ONC inclusion of dental records.

- Page 6: Preferred language should include written and spoken
- The sexual orientation needs to be added as a data class in years 2019 or 2020. Sexual orientation is not a data class in this document. This information is necessary for meeting the needs of our populations and is important in addressing suicide, violence, and addiction.
- Patient Address needs to be included in Common Clinical Data Set. This allows for better referrals, care, and understanding of access to healthy food, dentists, and other providers. Zip code matters, and is necessary to analyze health equity.

Candidate Data Classes under consideration

- Gender identity refers to 'how a person identifies' - <u>not</u> 'a persons self-perception'.

Emerging Data Classes under consideration

The social, psychological and behavioral data should be put into the Candidate Status Data. This information is important for addressing structural racism, advancing health equity, decreasing health and public health costs, and improving outcomes. In addition, country of origin and industry and occupation should be added to this list. Most of these data elements are proposed as part of the 2015 EHR certification requirements but not adopted.

ONC Requested Input Questions

1) **Are there particular eligibility requirements for the Recognized Coordinating Entity (RCE) that ONC should consider when developing the Cooperative Agreement?**

   Minnesota requests specific clarifications before eligibility requirements can be suggested:

   1) What will be the specific obligations of the RCE? The reference to definition and duties is limited at this time.

   2) What are the criteria for RCE selection?

   3) Will the RCE be charged with flushing out the next level of detail for the TEFCA (drafting common agreement) or will ONC have completed that before RCE FOA is issued?

   4) What are the minimum expectations for the HINs and Qualified HINs and how will this be accomplished through the RCE? How will current HIE investments be built upon with this framework?

   5) What are the general expectations for the RCE process to define the principles, requirements, etc.? Will this process be coordinated with ONC or a broader group of stakeholders and interested parties?

   6) The RCE must have experience working in, and/or staff with expertise in, the actors that are part of the four important outcomes (page 7). This is necessary to assure that a comprehensive trusted exchange framework is developed that

benefits all providers across the care continuum. This should include public health, community and social services, health care providers, and payers – not just HIT vendors/community.

2) Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?

No comments.

3) We recognize that important health data, such as that included in state Prescription Drug Monitoring Program (PDMPs), may reside outside of EHR/pharmacy systems. In such cases, standards-enabled integration between these systems may be necessary to advance, for example, interstate exchange and data completeness. As such, we invite comment on the following questions:

a. *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?*

- Should be consistent among states. Controlled substance fill information is currently pushed from distributors to the Minnesota Prescription Monitoring Program.

b. *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?*

- How would an interstate connectivity for PDMP data be enabled via a TEFCA use case work? Would there be a federal law? Would this pre-empt federal law for specifically opioid use-case data-sharing?
- How would the provider organization be held accountable? What would be the provider organization's obligation?
- State laws vary, which makes consistency difficult. Is ONC suggesting that state laws be superseded by federal law in this specific use case? How would this work? Would there be a consistent law?
- Access to medication history, regardless of where it comes from, is very important to patient safety and health, research, understanding medication and treatment compliance, and preventing the next prescription-based epidemic. Therefore, although thinking about the opioid epidemic is important, Minnesota cannot only focus on opioids as a reason to exchange medical information. We need to think how to address all of the issues related to medication/prescription misuse and abuse.
- Information sent to the PDMP for controlled substance analysis should also be incorporated into the individuals' consolidated health record – whether

this is determined to reside in a Qualified HIN or HIN. Since the HIN shares/connects that information to the provider, and investments have already been made for HINs to store and consolidate individual data, the HIN is the preferred choice.

- There is concern about a voluntary infrastructure such as the proposed TEFCA when the information to be shared is required and does not need the individuals' consent. A person could opt out of the HIN but not the PDMP, therefore a manual login may be required for the < 1% of patients that opt out. This applies to public health registries as well.

c. *Is there an existing entity or entities positioned to support the opioid use case directly either as a Qualified HIN within the draft Trusted Exchange Framework or within the proposed Trusted 6. Exchange Framework as a Participant of Qualified HINs? Is there an existing entity or entities positioned to support the opioid use case outside of the draft Trusted Exchange Framework? What is the readiness and feasibility of available standards to support the above and how have they been adopted to date?*

No comments.

d. *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*

- Minnesota suggests adding Population Health as one of the use cases and a primary reason for exchange of data through TEFCA. To avoid a constant process of querying for information, consider a model of patient centered data home, where specific information can be pushed to specific registries such as public health registries and the PDMP, when required, for further analysis. This population health analysis will analyze population health trends, outcomes, identify at-risk populations, and track progress for the specific focus area the registry is designed for.

In 2017, Minnesota Governor Dayton asked the e-Health Advisory Committee to provide recommendations for using e-health to prevent and respond to opioid misuse and overdose. One recommendation suggests the Governor support state agencies and stakeholders in participating in statewide coordinated health information exchange services. This recommendation ensures providers and public health have access to information to support individual and community health services, and supports:

- Alerts for emergency services, urgent care, and other medical visits relating to substance misuse and overdose.
- Referrals to substance abuse treatment and community services.
- Access to patient health history including medication lists.

The response to the Governor is available at http://www.health.state.mn.us/e-health/advcommittee/docs/recommendations.pdf

4) **When a federal agency's mission requires that it disseminate controlled unclassified information (CUI) to non-executive branch entities, but prohibits it from entering into a contractual arrangement, the agency is nevertheless directed to seek the entity's protection of CUI in accordance with Executive Order 13556, Controlled Unclassified Information, or any successor order, and the CUI Program regulations, which include requirements to comply with NIST SP 800-171. How best should TEFCA address these requirements?**

No comments.

Appendix A

2017-2018 Minnesota e-Health Advisory Committee Members

Alan Abramson, PhD, *Advisory Committee Co-Chair*, Senior Vice President, IS&T and Chief Information Officer HealthPartners Medical Group and Clinics
Representing: Health System CIOs

Bobbie McAdam, *Acting Advisory Committee Co-Chair*, Vice President, Information Technology, Medica
Representing: Health Plans

Sunny Ainley, Associate Dean, Center for Applied Learning Normandale Community College
Representing: HIT Education and Training
Co-Chair: e-Health Workforce Workgroup

Constantin Aliferis, MD, MS, PhD, FACMI, Chief Research Informatics Officer, University of Minnesota Academic Health Center
Representing: Academics and Clinical Research

Laurie Beyer-Kropuenske, JD, Director Community Services Divisions
Representing: Minnesota Department of Administration
Co-Chair: Privacy & Security Workgroup

Lynn Choromanski, PhD, RN-BC, Nursing Informatics Specialist, MVNA
Representing: Nurses

Cathy Gagne, RN, BSN, PHN, St. Paul-Ramsey Department of Public Health
Representing: Local Public Health

Maureen Ideker, MBA, RN, Director of Telehealth Essentia Health
Representing: Small and Critical Access Hospitals

Mark Jurkovich, DDS, MBA, Dentist, Gateway North Family Dental
Representing: Dentists

Paul Kleeberg, MD, Medical Director, Aledade
Representing: Physicians

Marty LaVenture, PhD, MPH, FACMI, Director Office of Health IT and e-Health, Minnesota Department of Health
Representing: Minnesota Department of Health

2017-2018 Minnesota e-Health Advisory Committee Members (continued)

Jennifer Lundblad, PhD, President and Chief Executive Officer, Stratis Health
Representing: Quality Improvement

Heather Petermann, Division Director, Health Care Research & Quality, Minnesota Department of Human Services
Representing: Minnesota Department of Human Services

Kevin Peterson, MD, Family Physician Phalen Village Clinic
Representing: Community Clinics and FQHCs

Peter Schuna, Chief Executive Officer, Pathway Health Services
Representing: Long Term Care
Co-Chair: Health Information Exchange Workgroup

Jonathan Shoemaker, Information Services Director of Clinical Application, Allina Health
Representing: Large Hospitals

Steve Simenson, BPharm, FAPhA, President and Managing Partner Goodrich Pharmacy
Representing: Pharmacists

Adam Stone, Chief Privacy Officer, Secure Digital Solutions
Representing: Expert in HIT

Meyrick Vaz, Vice President, Healthcare Solutions, Optum Global Solutions
Representing: Vendors

Cally Vinz, RN, Vice President, Health Care Improvement Institute For Clinical Systems Improvement
Representing: Clinical Guideline Development

Donna Watz, JD, Deputy General Counsel, Minnesota Department of Commerce
Representing: Minnesota Department of Commerce

John Whitington, South Country Health Alliance
Representing: Health Care Purchasers and Employers
Co-Chair: e-Health Workforce Workgroup

Ken Zaiken, Consumer Advocate
Representing: Consumers
Co-Chair: Consumer Engagement Workgroup

2017-2018 Minnesota e-Health Advisory Committee – Designated Alternates

Karl Anderson, Global Digital Health Senior Manager, Medtronic
Alternate Representing: Vendors

Robin Austin, DNP, Clinical Assistant Professor, University of Minnesota School of Nursing
Co-Chair: Consumer Engagement Workgroup

Sarah Cooley, MD, MS, Assistant Professor of Medicine, Division of Hematology, Oncology and Transplantations, University of Minnesota
Alternate Representing: Clinical Research

Kris Dudziak, CHCE, Senior Manager Business Operations, Home Care, Hospice, and Geriatric Services, HealthPartners Medical Group and Clinics
Alternate Representing: Home Health

Oyin Hansmeyer, Consultant
Alternate Representing: Experts in Health IT

George Klauser, Executive Director, Altair-ACO, Lutheran Social Services
Alternate Representing: Social Services

Sonja Short, Associate CMIO, Fairview Health Systems
Alternate Representing: Physicians

Mark Sonneborn, Vice President, Information Services, Minnesota Hospital Association
Alternate Representing: Hospitals

Susan Severson, Director, Health IT Services, Stratis Health
Alternate Representing: Quality Improvement

Ann Warner, Program Director, Data Governance & Analytic Education, Information Services HealthEast
Interim Co-Chair: Health Information Exchange Workgroup

LaVonne Wieland, Compliance and Privacy Officer, HealthEast
Co-Chair: Privacy & Security Workgroup