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Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, DC 20201
Via Email: exchangeframework@hhs.gov

Re: Comments on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft #2

Dear Dr. Rucker

Michigan Health Information Network Shared Services (MiHIN) appreciates the opportunity to submit comments on the second draft of the Trusted Exchange Framework and Common Agreement (TEFCA).

MiHIN is a non-profit organization, created to facilitate the exchange of electronic health information and build technical and collaborative partnerships between healthcare providers throughout the state of Michigan. From hospitals and providers, to pharmacies and payers, MiHIN creates the technology and state-of-the-art resources needed to ensure the electronic health records of Michigan citizens are available to all that deliver care services. MiHIN has been at the forefront of statewide interoperability efforts for almost a decade and is devoted to completing the natural progression toward nationwide interoperability.

MiHIN applauds the ONC's continued dedication to achieving nationwide interoperability. On average, U.S. citizens relocate every seven years. That means not only do individuals move across health care organizational boundaries for care, they also move across regional and state lines. Mobile populations increasingly rely on interoperability to ensure coordination of their care. Interoperability guarantees providers have all the pertinent information they need to make sound healthcare decisions at the point-of-care. When health information is available at the point-of-care, patients receive safe, efficient, high quality services and have better health outcomes. MiHIN stands with the ONC and looks forward to continuing to be an active partner in this process.

In large part, MiHIN is overwhelmingly pleased with the second draft of TEFCA. In our role as the State-Designated Entity in Michigan, MiHIN gathered comments from its stakeholders statewide and through discussions with a variety of national organizations. As a result, we have several salient observations and suggested ways to improve the TEFCA even further, as described herein.

MiHIN encourages ONC to review the following comments and recommendations to maximize the positive impact of the TEFCA on healthcare stakeholders.

Comments Organized by Principles for Trusted Exchange Framework

» Principle 1 - Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures

Recommendation: Utilize implementation guide for standardization. Data sharing agreements under TEFCA should require adherence to all relevant industry standards. This can be accomplished by creating and incorporating strict, unambiguous implementation guides. It is very important that all implementation details be kept separate from, but referred to by, legal agreements. Implementation guides, incorporated in this fashion, can change as standards change without requiring changes to the data sharing agreements themselves. Further, data sharing agreements under TEFCA should specify that conformance with standards will be measured and reported by the RCE to promote uniform compliance. While there are not financial incentives currently in place in TEFCA, such measures may increase an entity's willingness to participate in TEFCA. Finally, we recommend that Implementation Guides and conformance be the purview of the RCE and QHINs through multi-stakeholder governance rather than through the Interoperability Standards Advisory (ISA).

Recommendation: Provide sunset dates for older versions of FHIR. One recommendation emphasized in the second draft of TEFCA was the use of FHIR standards for query-based use cases. While MiHIN is completely in support of the use of FHIR to standardize communication between different resources, one point that must be considered is the multiple versions of FHIR that exist in the healthcare landscape. While MiHIN has built many solutions, such as our consent solution using FHIR 2.0, FHIR Release 4.0 has many changes from the older iterations and it may leave prior solutions outdated or unable to meet current standards. Furthermore, FHIR 4.0 is the first version that will be "backward compatible," which makes it the most sustainable option for ensuring that entities under TEFCA build an infrastructure *from inception* that will continue to be future compatible with new versions of FHIR. This would eliminate costly and time-consuming rebuilds of systems that could quickly become outdate and incompatible with each other. In order to truly create uniform processes, one specific release of FHIR must set the industry standards, and older versions should be phased out over time. If the ONC could provide sunset dates on these older versions, it would provide a proactive measure to a potential problem. Of course, sunset dates should be set reasonably, in timeframes that account for the time it will take to implement newer versions.

» Principle 2 - Transparency: Conduct all exchange openly and transparently

Recommendation: Provide bright line examples of information blocking. The ONC proposed rule, which has many complimentary components related to the second draft of TEFCA, cracks down on information blocking, while still allowing for seven tailored exceptions. While the exceptions will be important to account for the practical realities of health information exchange, ONC should outline examples of instances where a refusal to share information would or would not fall into the seven exceptions under the Trusted Exchange Framework. While TEFCA is distinct

from the ONC Proposed Rule, this component of the Proposed Rule will impact the practices of entities that participate in TEFCA. This is an important point because while TEFCA is currently voluntary, the 21st Century Cures Act is legally-binding and compliance with the law will influence the success of an otherwise voluntary framework. If entities are unable to provide information for any reason, or choose to not provide the information, bright line examples would give guidance on if these practices would constitute information blocking under the 21st Century Cures Act.

» 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

Fees: The TEFCA draft sets limits on the fees that QHINs can charge to other QHINs for data exchange. For example, QHINs may not charge other QHINs to respond to queries for Individual Access, Public Health, or Benefits Determination. We understand that high fees should not be a barrier to the exchange of data, however, we are equally concerned about cost burden incurred by QHINs to exchange data with no assessed fees for three of the six Exchange Purposes outlined in TEFCA. Increased expectations described in the framework will naturally result in higher operational costs for QHINs. Likewise, non-profit HINs and HIEs have expressed that they will be unable to participate in TEFCA specifications due to the high operational costs and limitations on assessed fees. To achieve the highest level of participation across all information exchange models, TEFCA should allow QHINs to determine their own fees in the initial stages of TEFCA, while HINs and HIEs that aspire to become QHINs develop and become efficient and sustainable. A reasonable fee structure is especially crucial in this framework, as there is currently no other financial incentive for HINs to become QHINs—a transition that will require a certain increase in workload and necessary resources.

Further, obligation to conform to a proposed fee structure that is new and untested introduces extreme risk into a market where some HINs and HIEs already have well-established fee structures that are successful, proven, and working business models. Likewise, requiring organizations that have known-working fee structures and fully-sustainability models to replace those financial models with an unknown, untested, and unproven fee structure could destroy the existing data sharing infrastructure already working in several states including Michigan. For those states that don't have sustainable models, relying on implementing an untested fee structure could compromise their viability if said fee structure fails.

Lastly, in a market-based economy where capitalism drives competition and innovation and regional markets differ, any regulation of fee structures seems counterproductive.

Recommendation: All references to fee structures be removed in the final version of TEFCA, and that <u>TEFCA remain fully silent on fees</u> in the final version, save for explicit language around non-discrimination.

An alternative is that any regulation of fees should follow a "crawl, walk, run" approach – start simple and with little or no regulation in early years until QHINs become established and stable. Revisit fees several years down the road when the initial QHINs and TEFCA are more stable.

Recommendation: Cooperation in Compliance Matters: Data sharing agreements under TEFCA should include mutual, bi-directional commitments to assist participating entities in fulfilling regulatory obligations as deemed appropriate. This includes responding to requests for reasonable information relating to the party's compliance efforts, security measures, and other areas. This has not been addressed in the TEFCA draft.

Recommendation: Clear Confidentiality Protections: Because business competitors are often concerned about proprietary information that may give a competitive advantage to another party, TEFCA should be very specific and unequivocal about confidentiality obligations by including industry-standard confidentiality provisions. This can avoid significant duplication between QHINs, and Participants, and Participant Members.

Recommendation: Dispute resolution: To maximize stakeholder collaboration among competitors, it may be necessary to establish a "safe place" whereby QHINs and the RCE can resolve disputes without litigation. This would require a formal dispute resolution process as part of all data sharing agreements. Binding dispute resolution provisions would prevent stakeholders from litigating against one another within the context of the data sharing agreements under TEFCA. This enables and fosters a trust environment in which data sharing can exist between competitors. When needed, aggrieved parties can submit their dispute to a committee constituted by a representative sample of stakeholders, such as executive representatives from each QHIN. A formal dispute resolution process ensures greater cooperation and transparency among participants, while providing a legitimate mechanism to address issues that may arise. Any dispute resolution process should provide for expedited handling of more urgent matters. Exceptions are appropriate for a potential disclosure of confidential information provided that the remedy is limited to injunctive relief. This formal dispute resolution process establishes a fundamental and essential trust fabric which becomes the foundation for ever-increasing levels of data sharing between trusted organizations. Michigan's successful dispute resolution structure has as its participants, United Healthcare, Aetna, Blue Cross Blue Shield, and 21 other health plans, thirteen (13) HIEs, the Michigan Department of Health and Human Services, and dozens of health systems, hospitals, physician organizations, and other Health Information Organizations throughout Michigan. Dispute resolution is an essential component for any large trust fabric or framework, based on empirical experience.

Dispute resolution has not been addressed in the TEFCA draft and should be both addressed and modelled after known working models to avoid tying up national interoperability efforts in endless litigation.

» Principle 4 - Security and Patient Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies

Recommendation: Obtaining Consent: Under the current framework, Participants will be responsible for obtaining individual patient consent. This requirement should be explicit in data sharing agreements under TEFCA, including QHIN Agreements and Participant Agreements. We support the requirement that QHINs should be named on paper and electronic consent forms as this comports with SAMHSA's 2018 Final Rule. This satisfies additional, and in some cases more

restrictive state regulations and mental health codes. At a minimum, QHINs should be provided copies with, or have query access to, information about consent (i.e. metadata) including patient demographics, named recipients, period of valid consent, and what information can be shared. If QHINs are provided a copy of this information about consent (consent metadata), this provides another layer of certainty when transmitting data between the QHIN and Participants, or between QHINS themselves. Query-able repositories for consent metadata are needed and it is likely that TEFCA and the RCE will need to specify requirements for "electronic Consent Management Services" that can be queried by QHINs to determine if valid consent exists for a person before sharing that person's data if it is "specially protected." Under this approach, QHINs can make the fact of existence of consent metadata electronically available to other QHINs upon request (find/query/pull) thereby allowing QHINs to share specially protected information if QHINs or their Participants are "named recipients." This capability has been demonstrated in the ONC's own Patient Choice Project. QHINs can maintain centralized consent metadata hubs/services within their markets. These eConsent management services should have open APIs so that other trusted Participants and QHINs may interact electronically by querying to determine if valid consent exists thereby enabling QHINs to share specially protected information electronically. This model also works for bridging the gap between Opt-out jurisdictions and Opt-In jurisdictions.

Recommendation: Requirement for electronic access to Consent Metadata: QHINs must be able to electronically query other QHINs to determine if valid consent metadata exists which allows specially protected information to be shared between QHINs or between QHINs and their Participants.

In the current paper-based environment, withdrawal of consent may be unrealistic in practice. A higher rate of success will be found when consent management services are implemented electronically with centralized consent registries that have standard APIs. TEFCA should differentiate between consent to use and disclose information *and* consent to permit exchange of patient information through a QHIN. These are separate consent requirements. There are many types of consent including but not limited to: consent to share health information (Release of Information (ROI) and HIPAA acknowledgement), consent to share information from Part 2 facilities, consent to research, consent to clinical trial, and advance directives (living will, DNR, organ donor, etc. are consents to act or not to act).

Recommendation: Comprehensive requirements on Consent/eConsent: TEFCA should be comprehensive on consent and clear in its move to electronic consent (eConsent) management. Michigan is developing a comprehensive consent solution which would account for both the electronic collection of consent at the provider level and the electronic check of consent before sending messages with SPI, which would occur at the HIN level. This two-part solution can be used as a model or jumping-off point for establishing a national, eConsent framework.

Recommendation: HITRUST Compliance for Security: We strongly advocate for TEFCA to require that QHINs be HITRUST certified. HITRUST collaborated with healthcare, technology, and information security leaders, to establish a Common Security Framework (CSF) used by all organizations that create, access, store or exchange sensitive, regulated data. The CSF harmonizes the requirements of multiple regulations and standards. HITRUST is highly esteemed

in the security realm for its ability to encompass a variety of other frameworks (Meaningful Use, HIPAA Omnibus Final Rule, NIST, PCI-DSS, FTC Red Flags, ISO 27001 1/2, and COBIT). Furthermore, requiring this level of certification across all QHINs would take some of the oversight/ compliance onus off of the RCE by creating a standard that can be verified by a simple "yes" or "no."

*Organizations not HITRUST certified create a gaping security hole in the trust fabric and introduce substantial vulnerabilities into the **entire "network of networks of networks."***

Recommendation: Liability for PHI: TEFCA should include an appropriate level of mutual liability for QHINs, as evidence of each parties' commitment to protect and use PHI solely for Exchange Purposes. Without appropriate levels of shared liability, obligations under data sharing agreements (including BAA) could be largely meaningless. In addition, the parties' liability should be capped at a reasonable amount, and liability insurance verified, with consequential and similar damages fully disclaimed. This approach is commensurate with industry practice and facilitates adoption of the program by others. Liability for PHI has not been adequately addressed by the TEFCA draft.

Recommendation: Disclosure Notification: Data sharing agreements under TEFCA should recognize that unauthorized disclosure of health information could potentially affect multiple stakeholders. Statutory or regulatory notification obligations are not always transparent when data is passing between covered entities via a chain of business associates and subcontractor business associates. TEFCA should require Participant notification practices that timely notify each other of potential unauthorized access, use, or disclosure of message content. This would ensure all parties can fully determine their legal obligations.

Recommendation: Cyber Liability: The cyber liability insurance market has matured significantly in recent years. Data sharing agreements for TEFCA should include very clear requirements for cyber liability insurance with specific amounts of coverage called out. This will ensure that all QHINs have liability limits necessary to address any potential liability issue that arises from data security breaches or unknown vulnerabilities. This has not been addressed in the TEFCA draft.

Recommendation: Intelligent, Accurate Routing For Re-Disclosures: Optimal patient safety requires that the right information, for the right person, be made available at the right place, and at the right time. This requires real-time highly accurate patient matching and push of data to the point-of-care. Where state or federal privacy restrictions exist, patient safety and privacy also mandate that data sharing agreements require strict adherence with consent and privacy laws, including re-disclosure disclaimers for sensitive substance use disorder data. This adds an additional layer of complication to accurate routing on top of accurate patient matching. Specific language surrounding these routing issues is of utmost importance in data sharing agreements. This has not been addressed in the TEFCA draft.

Recommendation: Provide guidance document on conflict of laws when states have different laws governing exchange or disclosure of EHI. Saying that the stricter law takes precedence will apply to some interstate exchange, but it does not account for conflicting laws. A guidance document that explicitly outlines procedures that QHINs should follow in the case of conflicting

laws is necessary to ensure exchange continues to happen rather than stop because entities are afraid of breaking a state law. Furthermore, it is unlikely that most future QHINs will have a comprehensive understanding of different state laws: a guidance document could help guide the formation of foundational interstate exchange models that takes conflict of laws into account from inception.

Recommendation: Clarify that TEFCA will *not* require QHINs to store EHI. The current draft of TEFCA says that QHINs are responsible for "maintaining" EHI. MiHIN fully supports maintaining EHI at the highest security levels to adequately move it from Point A to Point B. However, we only store EHI for a limited period of 90 days to ensure proper delivery and compliance with applicable laws. TEFCA should encourage a model that facilitates the *safe exchange* of data but should be careful not to create a model where massive amounts of patient data are aggregated at the QHIN level.

» Principle 5 - Access: Ensure that patients and their caregivers have easy access to their electronic health information

Recommendation: Provider access: Under TEFCA, data sharing agreements should require that data originators agree that any data they have or send may be shared with every active member of a patient's care team, subject to state and federal privacy and consent regulations and Exchange Purposes. This is, of course, dependent on the effective, accurate patient-provider matching across all QHINs.

Recommendation: Task the RCE & QHINs to demonstrate a working use case of national value: We strongly recommend that the RCE and early network of QHIN's be tasked with demonstrating the exchange of data via at least one common use case of national significance. Forcing an operational model early via a specific use case will ensure that the top down strategy envisioned for TEFCA does not become an overly burdensome paper tiger incapable of be operationalized at an interstate scale. It could also incentivize participation in this voluntary network by showing immediate value in the absence of any mandate or financial incentive to participation.

Recommendation: We recommend that the first data sharing scenario be an interstate Encounter Notification use case using a simple push model based on Admission, Discharge, and Transfer (ADT) notifications from at a minimum: hospitals, emergency departments, and skilled nursing facilities to prove that national interoperability is feasible.

While the original draft of TEFCA was entirely query based, this second draft introduced "push" or *message delivery* requirements for QHINs. MiHIN believes that both query and push are essential to the exchange of information, however, the most effective model would involve utilizing an "Alert & Query" model, where a member of a patient's active care team would first receive a pushed ADT alert that their patient has been admitted, discharged, or transferred to a health system. This alert would subsequently prompt an automated "query" to pull pertinent pieces of information about a patient from all QHINs to adequately coordinate that patient's care.

For example, the ADT alert generated from an emergency department visit can be used to trigger an automated query to the *RX Check* prescription drug monitoring system. Likewise, the same transaction can be used to establish patient identity and initiate a FHIR query to the other

hospitals and emergency departments the patient recently frequented. Finally, this same event notification can be routed to the public health department for syndromic surveillance purposes in a manner that supports both national security and public health

This "pure push" use case would serve as an incremental step to patient centered care coordination, and the subsequent query can be used to discover complex challenges required to enable broader levels of interstate interoperability. It would also serve as the starting point for higher levels of syndromic surveillance of national security value, and data enrichment linkages to solutions such as the patient centered data home or additional sources for patient data like distributed FHIR servers.

An ADT use case would set the precedent for the exchange purposes outlined in the Common Agreement and not only solve for transition of care and identity resolution challenges, but also remedy hurdles in public health syndromic surveillance.

In addition, this aligns with other national initiatives occurring simultaneously to the release of TEFCA. The 2019 CMS proposed rule requires admissions discharge and transfer (ADT) notifications to be sent for Medicare-participating hospitals, critical access hospitals, and psychiatric hospitals, however, we recommend expanding the scope of this requirement and leveraging this initiative to jumpstart a national initiative that applies beyond those three entities. With widespread support, and backing from the ONC and CMS, this "push" use case could be implemented in a short timeframe, creating an initial, national opportunity to achieve critical mass.

Recommendation: Provide clarity on which entities will be required to send Admissions Discharge and Transfer (ADT). Although the 2019 CMS Proposed Rule only states that Medicare-participating hospitals, critical access hospitals, and psychiatric hospitals will need to provide ADT notifications, the national TEFCA use case should expand the scope and clarify which other entities, if any, will be required to participate in ADT exchange. For example, it is unclear if emergency departments will be explicitly included in this iteration of the rule. If it has been purposefully left off, we recommend TEFCA include emergency departments and urgent care facilities to the list of entities that must provide these notifications. Oftentimes these are the individuals that need information at the point of care and to exclude them from this list would be problematic at a minimum.

Recommendation: Build on the existing bridges that Health Information Networks (HINs) and Health Information Exchanges (HIE) have built to support a national ADT use case. Existing Health Information Networks (HINs) and Health Information Exchanges (HIEs) should be used to facilitate the sharing of ADTs on a national basis. In Michigan, every hospital is currently participating in a Statewide ADT All Payer Use Case. This process has led to a huge economy of scale by standardizing the process of statewide alerting and removing the burden of determining who to notify from sending organizations. For example, to use MiHIN to scale the use case nationally would not require an exorbitant effort, however, it would be exceptionally damaging to our infrastructure if hospitals were now required to also send data through an additional path. We encourage specific modification to the rule to expressly permit organizations to utilize a HIN

or HIE for this purpose rather than requiring organizations to submit via an alternate or additional path.

Link: MiHIN ADT Notifications (https://mihin.org/tag/adt-notifications/)

Link: MiHIN ADT Use Case Summary (https://mihin.org/wp-content/uploads/2019/03/MiHIN-UCS-ADT-Notifications-v17-03-04-19.pdf)

Link: MiHIN ADT Implementation Guide (https://mihin.org/wp-content/uploads/2019/05/Microsoft-Word-MiHIN-UCIG-ADT-Notifications-v46-05-09-19.pdf)

Recommendation: Allow states to designate one entity where all Admissions Discharge and Transfer (ADT) messages should be sent. In order to minimize the burden on provider organizations, we recommend that each state designate one, sole entity where all ADT notifications should be sent. Depending on the connections organizations already have with HIEs or HINs, ADTs could either be submitted to these entities or directly to the QHIN. This will allow all organizations to fulfill their participation obligations through an efficient "send once" principle. An example of an entity that could accommodate the transmission of ADTs for the state is a designated QHIN, state designated entity, eHealthExchange hub, or similar entity.

Recommendation: Include a specific timeframe expectation for the transmission of Admissions Discharge and Transfer (ADT) messages. In MiHIN's experience, the timeliness of the ADT notification is imperative in emergency situations, where they may provide the greatest benefit. In Michigan's statewide use case, we have defined a timeframe in which the notification is required to be sent: 2 minutes. We suggest ONC publish specific timeframes for their ADT requirements as well.

Recommendation: Clarify which HL7 ADT Events are required. There are 51 different types of HL7 ADT messages that are used for various trigger events. ONC should utilize these preexisting types, but also clarify which of these ADT events will be required under this new requirement. As an example, some of the most commonly used ADT messages include:

- ADT-A01 – patient admit
- ADT-A02 – patient transfer
- ADT-A03 – patient discharge
- ADT-A04 – patient registration
- ADT-A05 – patient pre-admission
- ADT-A08 – patient information update
- ADT-A11 – cancel patient admit
- ADT-A12 – cancel patient transfer
- ADT-A13 – cancel patient discharge

Recommendation: ONC must formalize how active care relationships are established. MiHIN has created The Active Care Relationship Service®. The Active Care Relationship Service® (ACRS® – pronounced "acres") connects a patient's electronic health information with the providers "actively caring" for the patient as well as with the payers covering the cost of the patient's care. This connection improves transitions of care coordination and enables physicians and care management teams to receive notifications when there are updates in a patient's status. MiHIN's ACRS® can be used as a model to determine how active care relationships can be established.

Active care relationships are established in Michigan through provider organizations, who supply MiHIN with updated lists of all the patients they see on a monthly basis. While this component may seem straightforward, we have had to develop specific practices to keep patient-provider attributions up to date and accurate. This involves outlining procedures for providers to contest, confirm, and remove patients accordingly. ONC should provide clarity on how patient- provider attributions are established, contested, confirmed, expired, and removed in order to set industry best practices moving forward. Without accurate, up-to-date patient-provider attributions, patient information cannot be shared with all members of a patient's care team. In other words, even if an excellent use case were implemented to share patient information (ADT notification, SUD info, etc.), it is useless if it can't be accurately directed to the right care providers.

Recommendation: Develop a process to release ADT information to family members. While Michigan has been successful in sending ADT notifications from provider to provider or provider to payer, one area that leaves room for development is allowing family members access to ADT notifications. ONC should develop a process to dictate how patients can include family members as a part of their active care team so those individuals can receive important updates on a patient's health events. There is a coordination of care interest in providing this capability moving forward, as many times family members have the most comprehensive background on a patient's medical history.

Recommendation: Utilize Treatment, Payment, and Healthcare Operations (TPO) exception of HIPAA as governing principle for sharing ADT information. ADT messages can be shared without patient consent through the treatment, payment, and healthcare operations (TPO) exception outlined in HIPAA. ONC should use this as the governing principle for sharing ADT messages on a national basis. This will allow for the sharing of pertinent healthcare information at the point of care without the unnecessary, in this instance, step of obtaining patient consent.

Recommendation: Allow ADT notifications to integrate with syndromic surveillance, death notification, and certificate notification systems. ADT notifications can be routed to the public health department for syndromic surveillance, death notification, and certificate notification purposes in a manner that supports both national security and public health. We recommend ONC outline opportunities for this integration in the final rule released.

Link: MiHIN Syndromic Surveillance Use Case Summary (https://mihin.org/wp-content/uploads/2019/03/MiHIN-UCSS-Syndromic-Surveillance-v13-03-20-19.pdf)

Link: MiHIN Syndromic Surveillance Implementation Guide **(**https://mihin.org/wp-content/uploads/2019/04/Microsoft-Word-MiHIN-UCIG-Syndromics-Surveillance-v9-04-19-19.pdf0

Link: MiHIN Death Notifications Use Case Summary (https://mihin.org/wp-content/uploads/2019/03/MiHIN-UCS-Death-Notifications-v15-03-08-19.pdf)

Principle 6 – Population Level Data: Exchange multiple records for a cohort of individuals 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.

Recommendation - Specific data exchange: Data sharing agreements under TEFCA should account for smaller, discrete pieces of information sharing necessary to accomplish critical use case specific functions. Smaller data exchange or discreet messages (i.e., ADT notifications) are easy for new HINs and HIEs to adopt. Simple, discrete use cases allow for early wins, increase adoption, and gain momentum for more complex data sharing in the future. Rather than data sharing agreements that require "share everything" (which may make some entities, such as research hospitals, reticent), offer simple, "bite-sized" data sharing that can quickly 'fix' health care operation problems and require specific types of data (e.g. lab results, transitions of care, public health, quality information, provider information, patient-provider attributions, patient demographics, consent metadata, etc.) This modular, incremental design has not been incorporated in the TEFCA draft. A use case structure in TEFCA, subordinate to the categories of Exchange Purposes, could easily introduce a modular, incremental data sharing capability. We see this as a necessary prerequisite to being able to successfully achieve any meaningful national population or public health exchange.

Minimum Required Terms and Conditions (MRTC) for Trusted Exchange

» Definitions-

Recommendation- Require Standard Definitions Across Legal Agreements: While the MRTC does define a handful of terms used throughout the second draft of TEFCA, which will be essential moving forward, it may consider adding commonly used terms in healthcare to ensure alignment across the Common Agreement, QHIN-Participant Agreement, and Participant Member agreement. For example, even the way organizations define Confidentiality within health information exchange is oftentimes very different and may lead to misunderstandings if it is not clarified at this level. While we do not want to unjustifiably burden organizations to alter their existing agreements, alignment on definitions may be beneficial if changes will already be required.

» Initial Application, Onboarding, Designation and Operation of QHINs-

Recommendation- Clarify Timeline for QHIN Applications: While the second draft of TEFCA clearly outlines the process for applying to become a QHIN, signing the Common Agreement, becoming a "Provisional QHIN," being assigned to a cohort, and becoming a "Designated QHIN," it does not clarify whether entities can apply on a rolling basis, the length of time a QHIN remains "designated," how long the RCE has to respond to a QHIN application, or any ongoing requirements a QHIN must meet. Additional clarification on this process will help potential QHINs prepare for future requirements.

Meaningful Choice

Recommendation- Clarify Opt-Out Procedures: The second draft of TEFCA emphasized Meaningful Choice, and the ability for patients to opt out of health information exchange if they choose. Currently, each specific health information exchange or network dictates whether they have a formal opt-out policy for individuals. In Michigan, for example, MiHIN does not have a formal opt-out policy for individuals because individuals have not traditionally connected to MiHIN directly: only the individual's providers are connected to MiHIN. What has stopped us

from publishing a public opt-out procedure for individuals is the inability to identity proof individual users who would like to opt out. For that reason, we typically direct individuals to opt out at the provider level. While we understand the importance of public, transparent opt- out processes, concerns like this must be considered before requiring all QHINs to make this functionality available to a consumer.

Patient Access

Recommendation: Ensure patients are receiving healthcare information in a way that is beneficial to them. Patients should be able to easily access their healthcare information, at no charge to them through HIPAA's Right of Access rule. While patients undoubtedly have a right to their own healthcare information, it should be presented to them in a way, which allows them to understand the information they are being given and use that information to improve their quality of life.

Recommendation: Encourage creation of patient-friendly mobile technology. Health information technology developers must factor in ease of use and low health literacy. If these applications are built in a way that makes them difficult to maneuver, many patients may not take control of the features that the applications provide. Again, the surest way to determine exactly what will work for the population at-large is to form and utilize patient-focused focus groups to weigh in on how they would best be served by new technology.

Recommendation: Emphasize building an API, which would allow patients to direct their healthcare information from one provider to another. TEFCA emphasizes the right patients have to access all data utilized by their healthcare provider for treatment. While this right is certainly beneficial and outlines a key area where patient access will be needed, patients must have ability to direct their information from one provider to another. This is distinct from the right to provide information to the patients generally, because in this instance, the patient is not interested in the medical information itself, but merely in ensuring the appropriate providers receive the medical information. Both of these patient rights to information will go hand in hand and could certainly be facilitated through a sole mobile application, however there is value in explicitly building on this right to direct information from one point to another.

A stepping stone to building an application, which would allow patients to direct their information from one place to another, may center around a patient-provider attribution service which would allow patients to see all members of their active care team on their mobile application and direct information to them accordingly. MiHIN has conceptualized similar solutions utilizing our Active Care Relationship Service® (ACRS®) as a foundation. The Active Care Relationship Service® connects a patient's electronic health information with the providers "actively caring" for the patient as well as with the payers covering the cost of the patient's care. This connection improves transitions of care coordination and enables physicians and care management teams to receive notifications when there are updates in a patient's status.

Up until now, the use of ACRS has primarily functioned without direct interaction with the patient, however, with the use of consumer facing APIs and mobile applications, patients would

have the opportunity to update and maintain these relationships on their phone and subsequently ensure information is being routed to the appropriate individuals or entities.

Recommendation: Encourage creation of technology to automate or automatically push information to specific providers. As health information technology developers begin to create the resources for patients to control their own health information, they should be sure to factor in patient convenience. One way to do this is to allow patients the opportunity to set future preferences for "pushes" of their information. For example, a patient should be able to set a preference, which says, "in the future, always push my health information to the following individuals." This automation of information allows patients to set their preferences one time and eliminates an ongoing responsibility to update preferences for each new piece of information that might be sent.

» Data Quality and Minimum Necessary-

Recommendation: Support the use of the United States Core Data for Interoperability (USCDI) moving forward. MiHIN supports the exchange of data provided in the USCDI minimum data set, however, we believe that the timeline for the release of the USCDI must be accelerated. While the categories outlined in USCDI Phase 1 are undoubtedly crucial for patient care, there are many data field identified in USCDI Phase 2 and Phase 3 of the draft that will be imperative moving forward. For example, social determinants of health information are an area that desperately calls for a data field. Many players in the industry have used existing fields, allocated for different purposes, to track this data; however, to continue on this path will not allow for uniform, comprehensive collection of social determinants of health information. Categories like this must be accelerated into earlier phases of the USCDI in order to stay at the forefront of healthcare. ONC should make USCDI data classes standard in its final rule to align with the ONC proposed rule and second draft of TEFCA.

Recommendation: Incorporate use of unique identifier to eliminate patient matching errors. While it is important to electronically have access to current patient information at the point of care, it is equally important to ensure information attributed to the patient is correct. Simple errors in the entry of information, using a nickname, or the absence of a social security number, can all impact patient information and its successful transmission.

In Michigan, we have a solution to improve patient matching across organizations – Common Key Service. The "common key" is a unique, not human readable attribute assigned to every patient.

Organizations utilizing the Common Key Service are able to ensure they are talking about the same unique patient as an external identifier that can integrate within an existing electronic medical record system. In addition to improving patient identification, patient safety and care coordination is significantly improved using the common key. Additional benefits include reducing reliance on traditional patient identifiers, averting medical errors, improving fraud detection, identifying and resolve gaps in care, reducing burden on providers, and improving patient privacy and data integrity. Use of a unique patient identifier is essential to successfully executing a trusted exchange framework and will allow higher privacy standards for individual patients.

» Transparency-

Recommendation- Clarify transparent fee practices to differentiate between requirements surrounding the charging of fees and publishing fee schedules. We fully support the transparent processes outlined in the Trusted Exchange Framework and Minimum Required Terms and Conditions, however, our sentiments concerning Fee language outlined above still apply. While we do not believe the ONC or RCE should dictate the fees QHINs charge for their services, we understand and support the importance of transparent pricing practices. This includes the publication of general pricing information. However, it is imperative that if this requirement is in place, it should be in place for all players in the Trusted Exchange Framework to allow for competitive and fair practices.

» Cooperation and Non-Discrimination

Recommendation- Do not allow Participants to join multiple QHINs in order to avoid duplication. Under this framework, QHINs may not require exclusivity or otherwise prohibit any of its Participants from joining, exchanging EHI with, conducting other transactions with, using the services of, or supporting any other QHIN. While we understand the principle of cooperation under this framework, allowing Participants to join multiple QHINs may result in fragmented, duplicative efforts when attempting to coordinate the care of patients that fall within that Participant. The ONC must consider if this piece should be tailored to avoid inefficient processes moving forward.

» Privacy, Security, and Patient Safety

Recommendation- Consider the burden of oversight on voluntary QHINs. Under the updated framework Qualified Health Information Networks (QHINs) will take on a level of oversight that many of them may have not practiced thus far. Many HINs and HIEs do not examine the health information that they transmit, merely serving as a centralized mechanism to efficiently deliver information from Point A to Point B. The ONC introduces a "flow-down" method of oversight and accountability where the RCE will exercise oversight over the QHINs, the QHINs will be required to practice some level of oversight over its Participants, the Participants over the Participant Members, and so on. While this does seem logical in theory, it will impose a responsibility on QHINs that many of them have not accounted for in the past. The ONC must clarify exactly what QHINs are and are not responsible for with bright-line examples. This will ensure that QHINs are not held responsible for instances that they were unable to reasonably foresee. It will also limit the liability a QHIN may take on. Because this is a voluntary framework, imposing a strict oversight requirement, which may require the utilization of additional resources, could be an area that would deter otherwise capable HINs from participating.

» Participant Minimum Obligations

Recommendation- Determine appropriate notification processes. One responsibility imposed on a Participant is the requirement that the receiver of a QHIN Message Delivery ("push") send a notification to the sender that the message was received. While there is a benefit to providing such a notification, the RCE should publish in the final MRTC how to efficiently communicate these notifications from receiver to sender. For example, in a national framework, each entity

may send hundreds of thousands of messages per day, and an automated process will be crucial. In addition, it may not be conscionable to send each individual notification as a separate message; so, the ONC should provide guidance on if a sole notification with all messages received from one sender will suffice over a distinct time period (e.g. a day). Defining efficient processes, like this, early on will ensure a seamless exchange of information from the trusted exchange framework's inception. Furthermore, certain entities may only be set up to receive messages rather than transmit them. Requiring message receipt transmission may place an undue technological burden on these entities.

» Participant Member Minimum Obligations

Recommendation- Impose requirement on Participant Members, who are directly connected to Individual Users to provide transparent Meaningful Choice and Opt-Out practices: As was previously mentioned, Individual Users will be given much greater autonomy under the Trusted Exchange Framework to exercise their Right of Access to receive their own healthcare information, consent to sharing specially protected information, and Meaningful Choice to opt-out of health information exchange. Because Participant Members will be the only entities directly connected to an Individual User under this framework, they are appropriately positioned to communicate patient preferences to QHINs. While the QHINs may be required to publish opt-out practices publicly, and will undoubtedly honor a patient's preferences, Participant members will be able to control identity proofing to ensure patients are who they say they are and better manage patient preferences.

» Individual Rights and Obligations

Recommendation: Provide patient-friendly educational materials to Individual Users. While this draft allows patients to exercise many of their rights, including the right to receive a copy of each disclosure of their information that is made, it is necessary to also provide educational materials to patients on why this information is disclosed along with the importance of doing so. Many individuals may be under the assumption that their health information is being sold, used for marketing purposes, or for another purpose without their consent. This can prompt patients to opt-out of health information exchange even when the information is being used appropriately, to coordinate a patient's care and provide a comprehensive medical history to the patient's active care team. Educational materials on the importance and benefit of this coordination should be emphasized to allow for greater buy-in to TEFCA from patients themselves.

The Recognized Coordinating Entity (RCE)

Recommendation – RCE Selection: While the RCE will be a single entity, we recommend establishing a separate, multi-stakeholder team of QHINs to dictate best practices and take on the responsibility of approving edits to the TEFCA. A multi-stakeholder team of experienced entities may be effective to provide a check on the many practices that the RCE dictates.

A multi-stakeholder team, working in conjunction with the RCE and absorbing some of those key responsibilities, is likely the only way to get over industry-wide concerns and hesitations about a

potentially biased RCE and has the greatest chance of insuring broad, multi-stakeholder trust and participation.

We also encourage the ONC to revisit if one organization should hold such an immense power over the future of the Trusted Exchange Framework. It does not seem feasible that a single organization or vendor can serve as an objective RCE. There is great concern about selection of the wrong RCE; if the wrong organization is selected to become the RCE and even a remote sense of bias or favoritism is perceived, participation in TEFCA is highly unlikely to occur. In order to ensure trust in the framework, we recommend a balanced system of power distributed amongst the QHINs and other key players.

Stakeholder Collaboration: The RCE is tasked with creating the final Common Agreement. However, the RCE should finalize additional changes, only after soliciting input from the broadest mix of QHIN candidates, Participants, Participant Members, and covered entities alike. Data sharing agreements under TEFCA should include opportunities for stakeholder governance through an advisory committee and working groups. Entities that have entered into the appropriate data sharing agreements under TEFCA sharing should merit full inclusion in governance and all stakeholder decisions and communications.

Thank you for the opportunity to provide feedback on the TEFCA draft. If we can provide any additional information or clarification, please do not hesitate to contact me at Tim.Pletcher@mihin.org

Sincerely,

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