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Department of Health and Human Services
Office of the National Coordinator for
Health Information Technology
Attn: Governance RFI
Hubert M. Humphrey Bldg., Suite 729D
2000 Independence Ave. S.W.
Washington, D.C. 20201

Re: Nationwide Health Information Network: Conditions for Trusted Exchange

The following comments are being submitted to the "Nationwide Health Information Network: Conditions for Trusted Exchange" Request for Information ("RFI")[1] on behalf of the State of Illinois Health Information Exchange Authority ("Authority"). The Authority is an agency of the State of Illinois formed for the purpose of operating a State-level health information exchange in Illinois as a joint public-private initiative (the "ILHIE"). Illinois is a recipient of an American Recovery and Reconstruction Act ("ARRA") federal grant. Under the ONC's "State Health Information Exchange Cooperative Agreement Program", Illinois has been tasked with the development and implementation of the ILHIE.

Adequately formulating a comprehensive response to all of the 66 questions raised in the RFI was not possible within the limited response time provided. Accordingly, the following comments address selected principles reflected in the RFI that are of particular interest to the Authority.

Consistent National Leadership

The development and implementation of health information exchanges ("HIEs") across the U.S. are currently at a critical juncture. The Authority welcomes the ONC's issuance of the RFI and commends the ONC for seeking to provide the national guidance necessary to facilitate further development of the Nationwide Health Information Network ("NwHIN"). The Authority also welcomes the ONC's March 23, 2012 issuance of the Program Information Notice 003 ("PIN-003") entitled, "Privacy and Security Framework Requirements and Guidance for the State Health Information Exchange Cooperative Agreement Program"[2]. Because of PIN-003's close affiliation to the RFI, the following comments regarding the RFI will occasionally draw upon the discussion in PIN-003 of certain elements.

Consistent Federal leadership is welcomed and needed to address the legal and policy barriers that exist to the sharing of patient health data across State lines and to assure uniformly favorable health care outcomes in the U.S. wherever

[1] 77 Fed. Reg. no. 94, at 28543, Tuesday, May 15, 2012. (hereinafter "RFI"), available at: http://www.gpo.gov/fdsys/pkg/FR-2012-05-15/pdf/2012-11775.pdf.

[2] Program Information Notice—003, "Privacy and Security Framework Requirements and Guidance for the State Health Information Exchange Cooperative Agreement Program," March 2010, (hereinafter "PIN-003"), available at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_5545_1488_17157_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/onc_hie_pin_003_final.pdf.

patients are resident, including beneficiaries of Federally funded health care programs. The Federal government should recognize and accommodate the right of each State to decide the manner in which it may wish to advocate and advance the privacy and security interests of its health care providers and patients. However, the implementation of national health care policy and the efficient functioning of national inter-State exchange of health information necessitate Federal legislative solutions that preempt inconsistent, restrictive State policies. If the ONC is truly to enable the use of health information technology and health information exchange across the U.S. by 2014[3], the mere expansion of the NwHIN beyond its relatively small current membership will not suffice. The creation of an essential national infrastructure has in the past depended on the articulation of a national infrastructure vision, the engagement in national Congressional debate, and the enactment of corresponding Federal enabling statutes and regulations. The creation of a national health information exchange infrastructure calls for no less a Federal effort.

The Authority recognizes that the health care industry is constantly evolving, as are Federal health care policies. Regrettably, the ONC's long-anticipated RFI presents proposed policies that are inconsistent, in several important respects, with the previously issued ONC PIN 003 guidance. To the extent that the ONC is proposing departures from current Federal HIPAA law[4], such proposals are likely to attract the greatest support from health care industry stakeholders if the ONC's guidance is consistent and based on principles that enjoy broad health care industry acceptance.

For over ten years the health care industry has shared patient records for purposes of treatment, payment, and health care operations without patient consent, consistent with HIPAA's "T-P-O exception" provisions[5]. The HHS Office of Civil Rights has expressly stated in the past that a covered entity can utilize the T-P-O exception for disclosing PHI through an HIE "provided it has a business associate agreement with the HIO that requires the HIO to protect the information".[6] Whereas the December 2008 ONC Nationwide Security and Privacy Framework suggested that an individual's ability to choose whether his health data are included in an HIE is at the crux of building patient trust[7], it contained no proposed invalidation of the HIPAA T-P-O exception for data exchange through an HIE. Instead, the proposed invalidation of HIPAA's T-P-O exception appears for the first time in PIN-003. Specifically, PIN-003 proposes that with respect to most HIEs[8] patients be provided "individual choice" either in the form of an "opt-in" or an "opt-out", which represents a major revision to current HIPAA provisions. The RFI reiterates the requirement for "individual choice," [9] yet the RFI also provides that an exception to "individual choice" be created for purposes of "treatment". The ONC's apparent

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[3] The White House, President Barack Obama, "Affordable Care Act—Implementation Timeline," March, 2010, available at: http://www.whitehouse.gov/healthreform/timeline.

[4] RFI, infra at fn. 1, "The governance mechanism could include more prescriptive and/or more stringent policies that facilitate electronic exchange than are included in the HIPAA Privacy and Security Rule." (p.28545); "Existing Federal standards governing the privacy and security of health information establish an essential baseline of protection on which we anticipate building through nationwide health information network governance." (p. 28547); "The CTEs would establish additional requirements not currently addressed by the HIPAA Privacy and Security Rules." (p. 28553).

[5] 45 C.F.R. § 164.506.

[6] OCR, "Collection, Use, And Disclosure Limitation", a "companion document" to the ONC Framework, p. 4, FAQ #1, available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/collectionusedisclosure.pdf.

[7] "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information", p. 8 (hereinafter the "ONC Framework:"), available at: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.

[8] Attainment of the full potential benefits of health information exchange, particularly the fostering of data analytics to enhance health care delivery quality assessment and to foster medical advancement, requires the establishment of HIEs which are capable of more than mere secure point-to-point transmission of unstructured data. The ONC's artificial distinction between HIEs engaged solely in "directed exchange" (a/k/a "push" clinical messaging) compared to HIEs with query-response (a/k/a "pull") data exchange capabilities is further addressed below.

[9] RFI, infra at fn. 1, p. 28543.

opposition to the "T-P-O" exception in PIN-003 and its suggested "treatment" exception to "individual choice" in the RFI is inconsistent. This inconsistency raises questions about the extent of the ONC's commitment to such policy initiatives.

When the ONC's policies evolve, rendering current policy positions inconsistent with past positions, truthful dialogue with stakeholders is necessary. The ONC has finally acknowledged in the RFI that what was once the vision of the NHIN (now the NwHIN) as a "network of networks" with a recognized role for regional HIEs within a distributed federated network structure, has fundamentally changed. The ONC's promotion since 2010 of the NwHIN Direct secure messaging solution and other ONC initiatives has telegraphed the ONC's fundamental change of vision. However, without a truthful dialogue, the changes give rise to significant industry speculation, particularly as to the ONC's future support for sub-State regional/local HIE initiatives.[10] The ONC's recent official acknowledgement of the changed vision for the NwHIN is welcomed, but a complete examination by the ONC of the consequences for existing stakeholder initiatives and a truthful dialogue with affected stakeholders needs to occur soon. Such a dialogue would provide the ONC an opportunity to identify the specific space that publicly-operated HIE entity participants would occupy in the nationwide health information exchange topology, and to carefully consider the impact of proposed rules on the States.

Clinical Stakeholder Support

The Authority commends the ONC for attempting to engage broad stakeholder consideration of its policy initiatives. Whereas the direct audience for PIN-003 was relatively limited, the RFI will likely benefit from greater public visibility, as will eventual NPRM proceedings. Curtailed processes for stakeholder engagement detract from the merits of the ONC's proposals and undermine public trust and legitimacy for government processes and resulting outcomes. In this regard, the 45-day period provided for stakeholder comment to the RFI is insufficient for assuring the receipt of well-considered comments from a majority of interested stakeholders. The response period should be extended to 90 days. An extension would also allow for potential consideration of the Supreme Court's anticipated ruling regarding the constitutionality of the Patient Protection and Affordable Care Act within the next two months.

To avoid having its proposals discredited, the ONC should expand its scope of stakeholder involvement. In addition, the ONC should more clearly articulate compelling principles for amending current Federal HIPAA law in ways that fundamentally affect the health care delivery system at the point of care. These efforts would likely help the ONC to address any perceptions in the health care industry that its proposals are driven by partisan interests.[11]

The health care clinical professional community's full acceptance of the ONC's guidance is not just desirable, it is a necessary foundational precursor to the adoption of any policies that fundamentally affect health care clinical workflows. The ONC must provide neutral forums for all health care stakeholders to be heard. The U.S. health care delivery industry represents a significant component of our national economy, and engages public, not-for-profit, and

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[10] L. Lenert, D. Sundwall, M. Lenert, "Shifts in the architecture of the Nationwide Health Information Network", J. Am. Med. Inform. Assoc. (published on-line Jan. 21, 2012), available at: http://jamia.bmj.com/content/early/2012/01/21/amiajnl-2011-000442.full. We also respectfully note that the RFI's account of the NHIN evolution takes some liberties with historical facts.

[11] As noted by the Center for Democracy & Technology: "A consensus is emerging that quality health care depends on easy access to reliable and complete patient information... An earlier version of the [HIPAA Privacy] Rule did require consent for a broad range of uses and disclosures of personal health information, but the final version requires patient authorization for a narrower set of uses and disclosures....While at the time CDT's Health Privacy Project agreed with privacy advocates who vigorously opposed the narrowing of the consent requirement, our thinking has evolved....Unfortunately, discussions about how to provide privacy protections for electronic health information have been driven by those seeking to reinstate the consent provisions under the earlier version of the Privacy Rule. Focusing on what was "lost" in 2002 pits privacy against information sharing for important, core health care functions – and both are critical to reaping the benefits of health IT. Instead, health and privacy advocates must jointly advance policy solutions that both build public trust and promote the sharing of health information for treatment and improving our health system." Center for Democracy & Technology, "Rethinking the Role of Consent in Protecting Health Information Privacy", Jan. 2009, pgs. 1-6, available at: https://www.cdt.org/healthprivacy/20090126Consent.pdf.

private sector participants. The structure and future vitality of the U.S. health care delivery industry depend on the complex interrelationships of these participants, driven by different interests, values, risks, and rewards. Each industry participant adds value to our national health care delivery outcomes, and none should be discounted or excluded from our collective consideration of national health care policies, including those participants that provide health care products or services in the commercial marketplace for a profit. The ONC's policies that restrict participation of entities in the NwHIN or their access to and use of health care data should not be grounded in any form of discrimination against entities that function as commercial enterprises and earn profits from their delivery of necessary health care goods and services.

The views of health care clinical professionals need to be considered in the formulation of new health care policies. Even more so, their views should be incorporated into the ONC's balanced consideration of the relative costs and benefits of any new policy proposals. The valid concerns of patient privacy advocates should be considered by the ONC, but in the context of other compelling views and interests of all other stakeholders.[12] Any ONC policies that modify current Federal HIPAA law or fundamentally affect health care clinical workflows at the point of care should be grounded upon the following three core assumptions and objectives for HIEs:

1. Patient safety. Quality health care depends on providers having easy access to reliable and complete patient information.
2. Cost management. Better control over health care costs depends on the exchange of patient information among providers, payers and governmental bodies to facilitate care coordination, reduction of redundant treatment, and measurement of quality outcomes.
3. Medical advancement. Fostering innovation in clinical diagnosis and treatment and improving population health depend on the furnishing of patient data to medical researchers and public health authorities.

Articulation of Compelling Reasons

The ONC has failed to articulate compelling reasons for proposed amendments to current Federal HIPAA law that fundamentally affect the health care delivery system at the point of care. Most striking is the ONC's proposed invalidation of the T-P-O exception for patient data exchanges through most HIEs. This proposition would require that patients be provided "individual choice" (either "opt-in" or "opt"-out") each time a provider wants to exchange the patient information through most HIEs. Neither PIN-003 nor the RFI provides a compelling rationale for granting patients' "individual choice" when a health care provider utilizes a robust HIE to exchange patient data.

The ONC Framework (cited as the basis for PIN-003) only recites that the "ability of individuals to make choices with respect to electronic exchange of individually identifiable information concerning them is important to build trust".[13] No other rationale, compelling or otherwise, is provided. Why providers should collect "individual choice" for data transmissions through an HIE but no such workflow is required for data transmissions by fax should be explained. Even less understandable is the distinction made by the ONC between point-to-point HIE data transmissions, for which no "individual choice" is required, from transmissions through HIEs that "store, assemble or aggregate IIHI, such as longitudinal patient records with data from multiple providers", requiring "individual choice". In an attempt to distinguish between the two HIE models and determine that "patient choice is not required beyond existing law" where "HIE entities serve solely as information conduits", PIN-003 notes that "such sharing of IIHI from one health care

[12] Attached as an Appendix is a listing of the 16 factors proposed for consideration in the State of Illinois' submission to the ONC: "First Update – Illinois HIE Strategic & Operational Plan, Submitted by the Illinois Office of Health Information Technology, May 8, 2012", p. 36 ("Balancing of Interests").
[13] ONC Framework, infra at fn. 7, p. 8.

provider directly to another is currently within patient expectations".[14] However, the basis for such an assertion regarding "patient expectations" is not evident. Nor is it evident why or how "patient expectations" are or would be materially altered when a different model of HIE is used by a provider to exchange patient data, sufficiently to merit a material change to current law.

Use of Plain Language

In response to the creation and discussion of "NVEs" and "CTEs", we ask that the ONC refrain from creating new abbreviations except where absolutely necessary. Instead, please identify relevant participants and describe the processes for their participation in plain language. If new abbreviations must be created, please do not create or use terms closely related to already-established terms that are widely used and have generally understood definitions without a compelling reason (*e.g.,* "IIHI" in place of "PHI").

Environmental Assessment Needed

Almost every State has existing laws, regulations and enforcement mechanisms based on long standing local culture and requirements. There are likely many common features between States. A State-by-State assessment of existing laws, regulations, and enforcement mechanisms would identify these common features as they pertain to implementation of the NwHIN. Such an assessment might also serve to identify areas in which greater uniformity at the State level would significantly aid NwHIN implementation. Accordingly, we are of the opinion that an environmental assessment should be completed and analyzed before the ONC initiates an NPRM on NwHIN Governance.

Maturing of CoC and QI Needed

The "rules of the road" for collecting and exchanging relevant patient health information to foster coordination of care (CoC) and quality improvement (QI) are still in development at the National Quality Forum, the Physician Consortium for Performance Improvement, American Board of Internal Medicine/ American Board of Medical Specialties, and elsewhere. The Phase 1 draft report of the National Quality Forum Care Coordination Technical Expert Panel[15], an example of an HHS funded project, shows excellent progress, but further development is needed. We need to better understand the adopted fundamental transactions involved in CoC and QI before we can meaningfully consider the adoption of rules that govern the national network through which such transactions must flow. If we adopt rules for a rapidly evolving technology at its earliest stage, we risk stifling the chance for innovation.

National Standards Needed

We strongly support the establishment and enforcement of standards at the national level. National technical standards and implementation specifications are crucial to support true national interoperability of electronic health records.

Most helpful would first be to enumerate what technical standards should be included in the "conditions for trusted exchange" for entities that participate in the NwHIN, then to support an incremental approach to technical standards. However, rather than setting a broad range of loosely-defined standards and gradually tightening them (which is timely and costly), the ONC should start with only tightly defined standards and broaden them gradually. The ONC must reinforce that true interoperability requires strict adherence to well-defined standards.

Development of Interoperability Standards

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[14] PIN-003, infra at fn. 2, p. 6-7.

[15] http://www.qualityforum.org/HIT/Critical_Paths/Care_Coordination.aspx.

A standard set of policies for the development of interoperability standards is desirable. The details of the process should be well defined and highly specific.[16]

Actual interoperability criteria are important. That is, a pilot should be able to be interoperable with current standards without any customization of existing systems. Or, if a new standard is being proposed, the exact methods that will be used to bring existing systems into compliance would have to be part of the proposal along with an estimate of the costs that would have to be borne by different participants in existing information exchanges.

Focus of Standards and Interoperability Efforts

The ONC's standards initiatives should focus on the promotion of solutions that are generally recognized as advancing robust health information exchange. The development and implementation of Internet-based secure clinical messaging under the Direct Project messaging protocols may provide a valuable messaging alternative for providers without the capacity in the near term to adopt more robust electronic health record solutions and robust structured data exchange. However, there is currently not broad stakeholder support for the Direct Project in Illinois. The ONC's singular focus on the Direct Project specifications downplays the important and urgent task of facilitating the implementation of robust health information exchange, involving the exchange of structured data that supports data analytics which foster quality improvement and medical advancement.

Consideration should also be given to fostering the development of information technologies and services that enable the application of patient consent preferences to health information exchange. We need a specific set of metadata standards for describing patient consent preferences and an algorithm that specifies how to determine if a specific item of data is subject to a particular consent preference. We should also consider the eventual methods for storing and accessing patient consent preferences, as well as the nodes in the inter-State network topology at which to apply the algorithm to appropriately filter patient health data flows.

Governance and Federalism

How the NwHIN is governed is distinct and separate from how entities that become NwHIN participants are governed. Accordingly, we strongly oppose any attempt to impose Federal restrictions on the governance of State-level health information organizations, networks, or service entities. By contrast, we strongly support the ONC acting quickly and deliberately to establish a governance mechanism for the nationwide health information network and clearly articulating the benefits of participating in the NwHIN.

States, and usually not Federal authorities, license and regulate providers, insurers, employers, and other key stakeholders. There should be more clarity about the boundary between Federal and State authority in the implementation of the NwHIN. Consideration should also be given to securing the participation in the national HIE topology of State government entities which seek to foster the interests of all stakeholders and patients, including those who may be of marginal interest to private sector initiatives. Through Illinois' participation in the State Health Information Exchange Cooperative Agreement Program, the ILHIE is tasked with ensuring that every eligible health care provider has at least one option for health information exchange that meets the requirements of the Medicare and Medicaid EHR Meaningful Use Incentive Program. While there are several emerging sub-State regional and local HIE

[16] The development process should include, for example: a. Documentation of need; b. Approval of need; c. Requirements document; d. Certification test to be used to verify that a given implementation satisfies the requirements; e. Outcomes document that summarizes the pilot project and the value it provided; and f. Approval of outcomes document that can lead to an implementation standard.

initiatives in Illinois intending to launch live HIE operations in 2012, significant "white spaces" will exist in Illinois in which providers' only opportunity to secure health information exchange services is through the State-level ILHIE. The Authority also recognizes the potential of fragmentation and competition among various private sector HIE initiatives targeted at specific populations or data sets that may impede alignment and coordination steps necessary to facilitate HIEs. State-level HIEs can also enable and support important connectivity for State public health reporting and population health initiatives, and for the delivery by State agencies of health and human services, including Medicaid and population health initiatives.

Finally, State-level entities assuming oversight, accountability, and enforcement responsibilities can meaningfully enhance the conditions for public trust that patient interests are being protected, which is a precondition to HIE success. As the trust concerns of patients vary according to unique local conditions, including population demographics, health care marketplace dynamics, and HIE initiatives currently underway, State-level entities are best situated to assess and address the predominately local public trust needs of the residents of their States.

NwHIN Participant Validation

We support the idea that Federal programs participating in electronic health information exchange require the use of validated entities and incent State government programs to do the same. Also, we support the validation of entities to a set of conditions for trusted exchange and seek more public input about what would incent entities to become validated.

National Patient Risk Mitigation Strategies Needed

We strongly agree that the success of electronic health information exchange is largely dependent upon public confidence that the personal benefits outweigh the risks of personal harm arising from the misuse of personal health information. Greater consideration is needed of reducing the potential of patient harm arising from the wrongful use of patient health data. National legislation will likely be needed to address the wrongful use of patient health data in insurance coverage denials, employment discrimination, and reputational harms.

CTEs: Safeguards

[S-3]: *An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.*

First, as noted above under "Articulation of Compelling Principles" for what is a major departure from current HIPAA, neither PIN-003 nor the RFI provides a rationale for granting patients "individual choice" with respect to a provider's use of HIE for the exchange of patient data. Providers currently make decisions regarding both administrative office and clinical practice issues without a patient's involvement. Arguably these decisions are of greater significance than a provider's decision to exchange patient data through an HIE. During the ONC Tiger Team's deliberations at its August 19, 2010 meeting, an appointed member, Dr. Neal Calman, defended physician discretion to condition the delivery of patient-services on the patient's agreement to leave the administrative office practice details to the physician.[17] Dr. Calman's implicit questioning of the need to have patients approve a provider's use of HIE accurately reflects the

[17] HIT Policy Committee Meeting Final Transcript, August 19, 2010, pg. 31-32, available at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_947836_0_0_18/2010-08-19-policy-transcript.pdf; Anthony Guerra, "Contentious Privacy Recommendations Clear Committee," healthsystemcio.com, August 19, 2010, available at: http://healthsystemcio.com/2010/08/19/contentious-privacy-recommendation-clears-committee-hurdle/.

growing concern among clinicians that the implementation of new health information exchange technologies not entail new administrative burdens that interfere with clinical patient treatment and impose additional costs.

Second, as described under "Consistent and Visionary National Leadership", there is an inconsistency between the ONC's T-P-O position in PIN-003 compared to its position in the RFI. In the latter, the ONC acknowledges the prospect of allowing current provider workflow practices to continue with regard to the exchange of health care data for purposes of "treatment" without patient consent. Prominent patient privacy advocates such as the Center for Democracy and Technology have noted that the T-P-O exception under current HIPAA to further "core functions" of our health care system should be maintained.[18] The ONC needs to decide concretely how it stands on the "treatment" exception, but we highly encourage it to retain the current T-P-O exception as provided for by HIPAA.

Third, the proposed CTE requiring "meaningful choice" contains within it a number of complex underlying issues, several of which were individually identified in PIN-003. The issues that must be considered include: form of exercising patient choice ("opt-in" v. "opt-out"); manner of collecting patient choice; manner of informing patients of "meaningful choice"; granularity of patient choice; duration of consent; revocation of consent; application/verification of patient consent status; and reconciliation of conflicting patient consents. The concept of "meaningful choice" is highly subjective. Without concrete guidance or objective standards, it will be difficult for an HIE (or the provider at the point of care) to apply the requirement of "meaningful choice" to a particular patient encounter. The lack of objective certainty would be a burden on the provider's/HIE's decision-making process, which would result in increased costs. Significant additional work is required to advance the concept's operational implementation. In addition, having patients exercise choice at point of care places considerable burdens at the point of care. We strongly urge the ONC to explore alternative patient consent management options; e.g., collection of patient preferences via electronic portal; engagement of community organizations to promote and record patient preferences; and collection of patient consent preferences by payers.

[S-6]: *An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.*

The RFI suggests that NwHIN is opposed to "use [of] de-identified data for profit seeking opportunities" and seeks to prevent "commercialization of health information". But the RFI fails to provide the precise meaning of such precepts and the reason for imposing them on the NwHIN. It further reflects a hostility toward entities that function as commercial enterprises and earn profits from their delivery of necessary health care goods and services. Analysis of patient data and medical research should be encouraged to foster future advances in medical knowledge and improved patient care. Rather than limiting availability, Federal policies should encourage broad and non-discriminatory access to patient data, ensuring that relative wealth disparities among entities seeking such data are not used to distort the market for data access.

[S-7]: *An NVE must operate its services with high availability.*

The RFI defines "high availability" to be the equivalent of "24 hours x 7 days a week". Such "non-stop" computer database availability, currently provided by newer large-scale database services operators such as Google, Amazon, and Facebook, is possible in a multi-node network with distributed redundant databases. We agree with the need for "high

[18] CDT, infra at fn. 11, p. 4 ("Overall, this approach strikes the right balance between the needs of the health care system to access information and the rights of patients to exercise some control over this highly sensitive information.")

availability". However, to require compliance with such a data availability standard would require a major change to the legacy PHI storage topology in use today.

[S-8]: *If an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals with electronic access to their unique set of IIHI.*

The ILHIE currently has no direct relationship to the patient whose data are being transmitted. More importantly, the ILHIE has neither the authority nor the capability to exercise discretionary judgment in relation to clinical treatment, provider quality assessment, or claims payment. Rather, the ILHIE's function is to serve as conduit for message transmission between its data custodian users, which are HIPAA-defined and regulated "Covered Entities". HIEs are "Business Associates" rather than "Covered Entities" under current HIPAA, and it is neither necessary nor desirable to shift upon HIEs responsibilities involving the creation, alteration, or discretionary disclosure of the clinical content of transmitted messages. To the extent that new functionalities are desired within EHR systems to provide patients new or greater rights regarding data created at the point of interaction, the HIE is not the appropriate vehicle for driving EHR system change and adoption at the provider level. Changes to provider level EHR systems should be driven by uniform national standards, which should be incrementally applied.

Under current HIPAA, a patient's right to demand access to his data from a provider is conditional. A provider can reject a data access request if in the provider's judgment a disclosure may cause someone harm or compromise ongoing medical research. Such a determination presumably requires knowledge of relevant facts related to the demographic and clinical information contained in the patient record and the context of the request, and is presumably triggered in response to an access request. If a similar conditional access principle were applied to data access from an HIE, the HIE would presumably lack sufficient knowledge needed to deny access requests. Even if the HIE were to acquire the ability to analyze the clinical content of a patient record and appreciate the relevant context of the access request, the HIE does not have a professional clinical treatment relationship to any party or professional responsibilities that are enforced by licensing and disciplinary authorities. It is arguably undesirable, and potentially dangerous, to place responsibilities upon the HIE requiring the discretionary exercise of clinical judgment. The additional risk that the HIE would assume liability arising from unfortunate decisions would be difficult to quantify and insure against.

In addition, HIEs customarily transmit data to EHRs, which assemble, process, and display the data for the user. In order for a patient to view data from an HIE, the patient would need a Personal Health Record (PHR) or equivalent EHR software interface to view data from an HIE, or the HIE would need to provide a patient viewer/browser portal. The cost and burden of creating, managing, and maintaining such additional technologies needs to be considered.

[S-9]: *If an NVE assembles or aggregates health information which results in a unique set of IIHI, then it must provide individuals with the right to request a correction and/or annotation to this unique set of IIHI.*

Under current HIPAA, a patient's right to demand from a provider correction to data is conditional. A provider can reject a data correction request if the provider did not create the information or if in the provider's judgment the patient's record is "accurate and complete".[19] Such a determination presumably requires knowledge of relevant facts related to the demographic and clinical information contained in the patient record and the context of the request. If a similar conditional correction principle were applied to data correction by an HIE, the HIE did not create the clinical information and otherwise would presumably lack sufficient knowledge to assess correction requests for potential denial. As discussed above, even if the HIE were to acquire the ability to analyze the clinical content of a patient record and

[19] 45 C.F.R. § 164.526(a). Applying the authorship principle, an HIE should only correct data the HIE created.

appreciate the relevant context of the correction request, the HIE does not have a professional clinical treatment relationship to any party. Nor does the HIE have professional responsibilities that are enforced by licensing and disciplinary authorities. It is arguably undesirable, and potentially dangerous, to place responsibilities upon the HIE requiring the discretionary exercise of clinical judgment. The additional risk that the HIE would assume of liability arising from unfortunate decisions would be difficult to quantify and insure against. At best, the HIE can be required to forward correction requests and/or refer patients to the proper record custodian for consideration.

Further, many HIEs do not maintain repositories of clinical data. In most HIE distributed data models, the clinical data remain under the control of the original data custodian. The HIE transmits data that are either "pushed" or "pulled" from the distributed data locations. To be effective (i.e., persistent and ongoing), corrections to patient record data should be made at the data's point of origin. The HIE will presumably have limited control, at best, over data custodians and their handling of data correction requests. A viable option is for the HIE to advise patients which data custodian is the source of the suspect data in the patient's aggregated record, and refer the patient to that data custodian to initiate a data correction request in accordance with that provider's procedures.

Lastly, matching by an HIE of a specific individual to someone else's clinical data is a serious problem that the HIE will wish to investigate and rectify. Patient clinical data overlays, potentially resulting in clinical decisions based on the wrong data, can present a serious treatment risk to the patient. Such errors may arise because of patient identity theft and subsequent erroneous entries on the patient's record, or from mismatches arising from a provider's Master Patient Index (MPI) (or functionally equivalent computational patient matching method). To reduce its exposure to potential liability the HIE will wish to address erroneous matching. To investigate and rectify such errors effectively, a collaborative approach involving the relevant data custodians would need to be established.

[S-10]: *An NVE must have the means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a treatment relationship with that individual.*

PIN-003 and the RFI contemplate verification whether a treatment relationship exists. The ONC Framework on which PIN-003 is reportedly based contains no proposed change to current HIPAA [20] in this regard. However, it remains unclear whether the ONC is proposing that HIEs may no longer rely upon the current HIPAA's deference to the representations of providers.

CTEs: Interoperability

[I-1]: *An NVE must be able to facilitate secure electronic health information exchange in two circumstances: 1) when the sender and receiver are known; and 2) when the exchange occurs at the patient's direction.*

The prevailing standards (namely SOAP and SMTP) need to be supported, but these alone are not sufficient. The ONC needs to create standards for metadata such that the content of a message, while encrypted, can still be routed to all relevant endpoints. This will allow for the secure use and exchange of data without the need for redundant messages. Further, secure RESTful services should be supported, as should any new secure transport interface. In general, web interfaces should be decoupled from the back end services that support them. This might be better served by a recommendation rather than a requirement.

[I-2]: *An NVE must follow required standards for establishing and discovering digital certificates.*

[20] 45 C.F.R. § 164.514 (d)(3).

We agree that NVEs must follow required standards for establishing and discovering digital certificates. Without this requirement there will be no reliable way to establish trusted relationships. DNS and LDAP are global standards that we should continue to employ unless the W3C decides that other standards should be employed.

[I-3]: *An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.*

In order to promote national interoperability the IHE PIX and XDSb standards should be supported together with other standards supported by the IHE as they evolve. We are in favor of using the CDA R2 header formats as well. Matching algorithm accuracy should be very high (99+%). With respect to patient matching[21], we suggest VUHID as a national ASTM standard identifier with privacy classes.

CTEs: Business Practices

[BP-1]: *An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.*

[BP-2]: *An NVE must provide open access to the directory services it provides to enable planned electronic exchange.*

We support policies that encourage reciprocity between HIEs in order to facilitate the widespread exchange of data and connectivity among HIEs, particularly across State lines. Consideration must be given, however, to the financial implications of specific requirements on the sustainability of participants in the NwHIN. In particular, in the case of providing open access to directory services, how shall the expense of managing and maintaining an expensive directory be supported?

Conclusion

The Authority is committed to the development and implementation of HIEs in Illinois, and nationally, to improve patient health care outcomes, reduce costs, and improve population health and medical advancement. We welcome the ONC's national leadership to address legal and policy barriers that may impede the attainment of those goals.

Very truly yours,

Dr. Cheryl Whitaker
Chair, Illinois Health Information Exchange Authority

enc.
cc: Governor Pat Quinn

[21] Core data elements we are using are: a. Last Name; b. First Name; c. SSN; d. Gender; e. Birth Date; f. Street Address; g. City; h. State; i. Zip code.

Appendix A: Balancing of Interests

The implementation of measures intended to increase public trust must be balanced against cost and other considerations and interests. Relevant factors in such a balancing analysis include:

1. extent of benefit to the majority of patients;
2. extent of additional effort and cost (initial and ongoing) to the HIEs, providers and HIE users;
3. Maximize seamless flow of data to where needed for patient interaction, treatment, or care coordination;
4. Foster physician trust in the completeness and accuracy of HIE-provided data;
5. Encourage coordination of care, reduction of medical treatment errors, and improve health care and patient safety;
6. Enhance public health reporting, population health and medical research;
7. Avoid unnecessary duplication, increasing efficiency, and reducing health care system costs;
8. Minimize burdens, particularly administrative ones, upon health care professionals;
9. Avoid the potential for conflicting outcomes between HIEs and providers regarding patient rights, and the possibility of patient rights "arbitrage" between HIEs and providers;
10. Avoid interference with clinical decision-making by providers;
11. Avoid data access restrictions which discriminate between health care professionals;
12. Encourage the evolution of current state of technology, without imposing adoption of operationally untested technologies and concepts;
13. Encourage adoption of new technologies and concepts through incremental implementation;
14. Encourage EHR ease of use and user adoption;
15. Encourage user HIE adoption and HIE sustainability;
16. Deter fraud and criminal activity, including patient concealment of drug abuse and diversion.