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May 29, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Governance RFI
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW.
Washington, DC 20201

To Whom It May Concern:

HLN Consulting, LLC is pleased to submit the enclosed response to the Nationwide Health Information Network: Conditions for Trusted Exchange Request for information (45 CFR Part 171) as posted in the *Federal Register* on May 15, 2012. HLN is a leading health information technology services company which has been supporting health IT projects particularly for public health agencies for more than 15 years. We have also been involved in Health Information Exchange support, activities, and standards development/harmonization for the past several years.

We have chosen to respond only to select questions. Should you require any clarification on our responses please feel free to e-mail me directly at arzt@hln.com or to call me at 858-538-2220.

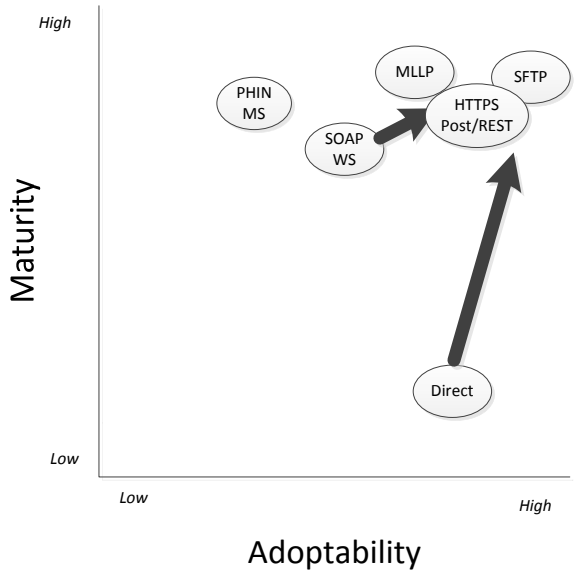
Sincerely,

Noam H. Arzt, Ph.D.
President

enclosure

Question	Response
Question 14: Should there be an eligibility criterion that requires an entity to have prior electronic exchange experience or a certain number of participants it serves?	We worry about a Catch 22: If NVEs are required to have "time under their belts" of providing services, early customers will be required to sign on to an HIE who is *not* certified. Will that make it harder for HIOs to get off the ground? Maybe an HIO should be able to become an NVE based on its acceptance of the CTEs in principle not necessarily on specific track record. Or maybe there could be some kind of provisional certification so a new HIO can at least start off on the right foot.
Question 27: In accommodating various meaningful choice approaches (e.g., opt-in, opt-out, or some combination of the two), what would be the operational challenges for each approach? What types of criteria could we use for validating meaningful choice under each approach? Considering some States have already established certain "choice" policies, how could we ensure consistency in implementing this CTE?	We have seen many operational challenges to consent policy with HIEs today. Much of it stems from a desire (by the consumer) and/or a requirement (by Federal, State or local law) to restrict movement of health information without positive consent based on the subject matter of the data regardless of the desired consent policy of the HIO. We do not have practical methods to distinguish consistently when data is of a restricted type. And we do not have adequate tools to manage the assignment, modification, and revocation of consent as required by the hodge-podge of laws. One solution to this in the context of CTE Condition S-3 is to allow some flexibility – varying by region, state, and HIO – as to the meaning of "meaningful choice" to allow for local variations and needs. This may seem like a softening of the requirement but we feel it is the only practical approach.
Question 37: What impact, if any, would this CTE have on various evolving business models? Would the additional trust gained from this CTE outweigh the potential impact on these models?	The most problematic aspect of this CTE is the lack of a definition of "commercial." Given that some NVEs are inherently for-profit entities (or could be), we worry that this blanket prohibition may apply to core activities the NVE is conducting with full disclosure to its members and participants. Is this CTE meant to ensure that *all* NVEs are not-for-profit entities? Many hospitals are for-profit and are constructing "private" HIEs.
Question 39: What standard of availability, if any, is appropriate?	We are concerned that imposing any external measure of availability will require NVEs to provide levels of service that may not be required for their particular service model or offerings. We could certainly envision HIE activities which would not *require* 24x7 operations.

Question	Response
Question 40: What further parameters, if any, should be placed on what constitutes a "unique set of IIHI"?	We are uncertain that any set of IIHI assembled by an NVE is really unique in the way it is described in the text of the RFI, or that its uniqueness warrants a requirement that patient access be provided. We would be suspicious of any IIHI that could be so altered by an NVE that a patient could not reconstruct it (albeit with some effort) from the original data which could be acquired from the participating sources. We feel it may be sufficient for an NVE to audit and provide on demand (and based on a verified identity) the organizational *sources* of information in a patient's record for direct follow-up by the patient.
Question 42: Are there any circumstances where an NVE should not be required to provide individuals with the ability to correct their IIHI?	Given our response to Question 40 above, we are concerned about the NVE becoming the authoritative source of health information when in fact the originating electronic health records should be that source (with the exception of IIHI actually typed into an interactive application provided solely by the NVE). The patient should be required to pursue correction of the data with the *original source* of the data and not the NVE. That being said, we believe that NVEs should be expected to tag records about which a patient has raised a question in such a way that subsequent viewers of queries which might include that data understand that a question has been raised. The choice to consider that data equally with untagged data should rest with the recipient of the data.
Question 44: Are there circumstances where a provider should be allowed access through the NVE to the health information of one or more individuals with whom it does **not** have a treatment relationship for the purpose of treating one of its patients?	We are quite concerned that the text of the RFI around CET Condition S-10 seems to recognize only treatment as a legitimate goal of HIE, and therefore by implication other types of activities which are not covered by this CTE (or any other) appear less legitimate. HIPAA stipulates treatment, *payment and operations* and all of these should be legitimate reasons for health information exchange (subject to law). HITECH itself identifies a whole host of additional reasons why health information and health information exchange should be undertaken – all of this should be considered here.

Question	Response
Question 45: What types of transport methods/standards should NVEs be able to support? Should they support both types of transport methods/standards (i.e., SMTP and SOAP), or should they only have to meet one of the two as well as have a way to translate (e.g., XDR/XDM)? **Question 46:** If a secure "RESTful" transport specification is developed during the course of this rulemaking, should we also propose it as a way of demonstrating compliance with this CTE?	Transport is a tricky issue. We are currently working with the International Society for Disease Surveillance and the Centers for Disease Control and Prevention on specifications for ambulatory and inpatient syndromic surveillance. One part of our work is to identify, discuss, and recommend transport strategies for data submission to public health agencies in this context, but this submission is typical of connectivity in general. We have made several observations about the use and robustness of certain transport strategies being used by providers today to exchange data with public health, and we have drawn the following diagram based on the RFI's own notions of technology maturity versus adoptability:  We observed that hospital connections to public health have often been in place for some time and are typified by virtual private network (VPN) connections that support a number of protocols, including SFTP, MLLP, HTTPS POST. PHINMS (a CDC creation based on ebXML) is established but diminishing; SOAP-based web services (especially for bi-directional exchange) and Direct (for uni-directional exchange) are not yet widely used but are on the rise. In addition, While most public health reporting relationships exist directly between public health agencies and the reporting provider or hospital, HIEs have begun to intermediate in public health reporting services, though

Question	Response
	usually relying on existing means of connectivity at least initially. Many HIEs rely on proprietary vendor protocols delivered over VPN connections. Some HIEs provide value-added services (such as semantic coding or message filtering) while others simply transport the data from source to destination. Different use cases require different architectures and different styles of data transport:  We also note that there is a tension between the desire to choose the correct architecture and transport for a particular need, versus the risk that an organization will end up with too many architectures to support. This reality may force some necessary compromises simply to reduce the number of protocols and strategies being used by organizations, like the use of a more sophisticated technology for a relatively simple task (*e.g.,* using SOAP-based web services merely to carry a uni-directional immunization report to public health), or trying to use a simpler technology for a more sophisticated task (*e.g.,* using a pair of asynchronous Direct messages to simulate a query/response). We do not believe that particular transport strategies should be mandated for HIE. Different use cases require different strategies. And the history and character of the organizations involved in an HIE project need to drive the choices that are made. To be sure, compatibility with *de facto* or emerging standards is important, but HIEs are in a good position to provide the necessary gateways and translations for their members. It may be instructive to review the deliberations and conclusions of the CDC-convened Immunization Information Systems (IIS) Transport Layer Expert Panel which struggled with many of these issues. The primary drivers for their selection were the suitability of the transport for bi-directional interoperability,

Question	Response
	the ability of IIS to implement the protocol, *and* the expectation that EHR system vendors could implement the protocol as well.[1]
Question 47: Are the technical specifications (i.e., Domain Name System (DNS) and the Lightweight Directory Access Protocol (LDAP)) appropriate and sufficient for enabling easy location of organizational certificates? Are there other specifications that we should also consider? **Question 48:** Should this CTE require all participants engaged in planned electronic exchange to obtain an organizational (or group) digital certificate consistent with the policies of the Federal Bridge42?	With respect to Direct, it is not clear to us why every organization (let alone every person) using Direct needs a digital certificate, nor that every Direct implementation needs to be done in this way. If using a HISP, we feel it should be sufficient for the HISP's global certificate to provide the encryption necessary for secure transport. Requiring digital certificates for all participants seems to go against the original goals of direct: keep it simple, keep it easy to deploy. A user should be able to use a directory to find a direct *address* and the HISP should take care of the rest.
Question 49: Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to certain minimum ratio? What should the required levels be?	We have worked on patient matching issues in public health for many years: public health registries (like IIS) have functioned as proto-HIEs for some time. In addition, we are currently participating on the CDC's Patient Data De-duplication Expert Panel.[2] The issues surrounding accurate matching in a large patient population are significant – the use of a unique patient identifier would certainly improve the accuracy of matching in an HIE, as well as the use of broader sets of fields for matching (demographic *and* clinical), special strategies for particular subsets of the population (*e.g.,* common name patterns in certain ethnic populations), special strategies for children from multiple births, and the like. That being said, we do not believe that an arbitrary accuracy target will be particularly beneficial. In fact, we do not believe that accuracy metrics ar even possible in many settings. Some patient populations are easier to match than others. Sometimes not even a human can determine whether a record pair is a match or not.

[1] See http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html#technical
[2] See http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html#patient

Question	Response
Question 50: What core data elements should be included for patient matching queries?	Different use cases may have different requirements, but in our extensive work in this arena with public health agencies we have found that *at minimum* the following fields should be used for patient matching: first name, last name, date of birth, gender. Other fields (including in some cases clinical data itself) certainly improve the likelihood of a correct match.
Question 51: What standards should we consider for patient matching queries?	We do not believe there are any existing relevant standards for patient matching.
Question 54: Under what circumstances, if any, should an NVE be permitted to impose requirements on other NVEs?	Though not a financial requirement, we expect that one NVE may place specific preconditions on another NVE with respect to patient privacy and consent. It may be, for instance, that as a precondition to receiving data from a sending NVE, the receiving NVE may have to agree to filter specific data that may not meet certain consent rules before delivering it to its final destination. Similarly, a receiving NVE may require a sending NVE *not* to send certain data without consent, or not to send data with a particular consent policy or attribute tagging attached.
Question 55: What data would be most useful to be collected? How should it be made available to the public? Should NVEs be required to report on the transaction volume by end user type (e.g., provider, lab, public health, patient, etc)?	While user and transaction volume information would certainly be useful, we do not believe an NVE should be *required* to provide that information to the public or anyone else. While HIE is an inherently cooperative activity many NVEs are likely to be private, even for-profit entities which should not be required to disclose this information and potentially jeopardize their business model or activities.
Question 56: Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should also consider?	See responses above.

Question	Response
Question 64: Would this approach for classifying technical standards and implementation specification be effective for updating and refreshing Interoperability CTEs?	The approach seems reasonable, but we feel it would be beneficial for ONC to provide concrete examples of standards in each quadrant of Figure 1 to better explain how it classifies different standards.