

GOVERNANCE WORKGROUP COMMENTS ON LIST OF CTEs

June 6, 2012

**CTE Category: Safeguards**

CTE	Suggested Changes
[S-1]: An NVE must comply with sections 164.308, 164.310, 164.312, and 164.316 of title 45 of the Code of Federal Regulations as if it were a covered entity, and must treat all implementation specifications included within sections 164.308, 164.310, and 164.312 as “required.”	No changes.
[S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.	Need clarification on the concepts of “authenticated” “authorized”, and “directly or indirectly”
[S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.	The final interpretation of “meaningful” must take into account realistic financial constraints as well as the fact that most people don’t want to have a complicated system explained to them.
[S-4]: An NVE must only exchange encrypted IIHI.	No changes.
[S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.	The “to whom” should not require the publication of its customers/Members. That is proprietary data.
[S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.	No changes
[S-7]: An NVE must operate its services with high availability.	Define “high availability” with the understanding that it means more than just that the interface is working... the software behind the interface also has to work (which is much more difficult to measure)
[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.	NVEs must be allowed to determine the best way for each of them to comply... this is not a ‘one-size-fits-all’ solution

CTE	Suggested Changes
<p>[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.</p>	<p>Delete.</p> <p>If the NVE is a covered entity such as a healthcare provider, then the HIPAA regulations already require this.</p> <p>If the NVE is an HIO, then it is inappropriate for the HIO to do this as it is never the source of the data. Often the only entity that can do the correction is downstream; or a correction made upstream may not flow downstream.</p> <p>HIPAA clearly places this responsibility on providers. It needs to stay there.</p>
<p>[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. Interoperability</p>	<p>Delete.but work towards a different version of this concept.</p> <p>If the NVE is a healthcare provider, then they are already required under HIPAA to be responsible to ensuring appropriate use and disclosure of PHI. The large organizations struggle with this as it is very difficult to do.</p> <p>If the NVE is an HIO, then, yes, the NVE must require that providers attest to a treatment relationship with the patient but the liability about VERIFYING that relationship belongs to the providers. There is no practical way an HIO can verify this relationship.</p> <p>See above comments about not requiring "legitimate purpose" for validating an NVE.</p>

## CTE Category: Interoperability

CTE	Suggested Changes
<p>[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.</p>	<p>Delete for now. This concept is important but it needs discussion.</p> <p>Problems with the current language include:</p> <ol style="list-style-type: none"> <li>1. This appears to only address directed exchange. What about exchanges where the sender and receiver are not known? For example, the VA queries the UHIN HIE, they do not know which providers are going to respond. UHIN gives the VA an composite CCD with data from every provider who had information about that patient in the Utah HIE. The VA may not know in advance exactly who they are.</li> <li>2. What does it mean "when the exchange occurs at the patient's direction"? is this an active or a passive direction? What about if the exchange is required by law (e.g. public health reporting)?</li> <li>3. Perhaps "or" rather than "and."</li> </ol>
<p>[I-2]: An NVE must follow required standards for establishing and discovering digital certificates.</p>	<p>No change</p>
<p>[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.</p>	<p>Needs more thought.</p> <p>Needs a determination of exactly what type(s) of data exchange would be governed by the NwHIN Governance structure. Workgroup repeats that Interoperability CTEs need to be modular. Absent a process for determining what the proper starter set is, it is hard to comment on what should be here. Need mechanism for determining priority policy-level interoperability goals.</p> <p>This appears to address record locator services (RLS), which seems appropriate to fall under governance. Does it exclude exchanges that don't involve an MPI? What about users of Direct? The NVE has no role in verifying/matching the patients.</p>

## CTE Category: Business

CTE	Suggested Changes
[BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.	Delete. The HIE Market is too nascent to begin to have the federal government set pricing rules. Hang on to this concept but don't use it at the beginning.
[BP-2]: An NVE must provide open access to the directory services it provides to enable planned electronic exchange.	Workgroup did not reach consensus. One member felt that it depends on meaning of 'open access to the directory services.' Companies must be able to guard their customer lists.  Others felt that if the intent is limited to directed exchange, this is critical and reflects net neutrality criteria.
[BP-3]: An NVE must report on users and transaction volume for validated services.	Workgroup did not reach consensus. Some prefer aggregation at lower level as well as at governance level; others are comfortable if NVEs report detailed data and aggregation is at level of governance entity. See answer to Q 55.