

# Nationwide Health Information Network: Conditions for Trusted Exchange Request For Information (RFI)

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# Take it from the top

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- Statutory authority
  - PHSA Section 3001(c)(8) requires the National Coordinator to “establish a governance mechanism for the nationwide health information network.”

# What is the nationwide health information network?

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- A set of standards, services, and policies that enable secure health information exchange over the Internet.

# Why act now to establish a governance mechanism?

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- Electronic health information exchange addresses a critical need in our healthcare system and provides the foundation for improved care coordination and quality improvement.
- The speed with which electronic health information will be exchanged will be at the “speed of trust.”
- We need to a common set of rules (expressing technical, privacy and security, and business practice requirements) to create a consistent trust baseline for stakeholders.
- In the absence of national guidance, States and other private sector stakeholders/consortiums are beginning to develop State/consortium-unique and potentially conflicting governance approaches to electronic health information exchange.

# Overall Governance Mechanism Objectives

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- Enable a more competitive and open market for electronic health information exchange and make it more efficient for these entities to exchange electronic health information.
- Relieve burden States who are taking on disparate governance approaches.
- To lay the foundation necessary to support future stages of meaningful use.
- To work with the HIE marketplace to coordinate and guide the maturation and evolution of standards and interoperability activities over time.

# The RFI – Bird’s-eye view

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- Focused on entities who facilitate electronic health information exchange.
- Discusses a voluntary framework
- Seeks comment on 5 areas:
  1. The establishment of a set of conditions for trusted exchange (CTEs) – “rules of the road”
  2. A validation process for entities to demonstrate conformance to the CTEs (and subsequently become an NVE)
  3. Processes to update and retire CTEs
  4. Establishment of a process to classify the readiness of technical standards and implementation specifications to support interoperability related CTEs
  5. Approaches for monitoring and transparent oversight

# Conditions for Trusted Exchange

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Safeguards CTEs: focus on the protection of individually identifiable health information (IIHI) to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure.

Interoperability CTEs: focus on the technical standards and implementation specifications needed for exchanging electronic health information.

Business Practices CTEs: focus on the operational and financial practices to which NVEs would need to adhere in support of trusted electronic health information exchange.

# Conditions for Trusted Exchange

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## Safeguards CTEs

**[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.”

**[S-2]:** An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either 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.

**[S-4]:** An NVE must only exchange encrypted IIHI.

**[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.

# Conditions for Trusted Exchange

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## Safeguards CTEs

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

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

**[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.

**[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.

**[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.

# Conditions for Trusted Exchange

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## 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.

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

**[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.

# Conditions for Trusted Exchange

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## 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.

**[BP-3]:** An NVE must report on users and transaction volume for validated services.

# Eligibility Criteria to Become an NVE

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- The RFI specifies a list of potential preconditions that would apply to entities seeking to become a nationwide health information network validated entity (NVE).
- If the preconditions are met, the entity would be able to continue to seek validation.
- We anticipate that eligible entities may include (but not limited to):
  - EHR developers;
  - Integrated delivery networks;
  - Regional, state, local or specialty-based health information exchanges;
  - Health information service providers;
  - State and Federal agencies.

# Validation

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- Validation could consist of:
  - Testing/certification of products or technology (interoperability CTEs); and
  - Accreditation of services (safeguard and business practice CTEs).
- ONC would select an Accreditation Body to accredit Validation Bodies, who would be authorized to validate an entities CTE compliance.
- If an entity successfully completes the validation process they would become an NVE.

# Process to Update and Retire CTEs

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- The purpose of this process would be to identify and assess current electronic exchange needs and to provide a path for determining how best to address them through the CTEs.
- We believe that an inclusive and transparent process to identify, modify, and retire CTEs would be needed.
- Classification:
  - “Emerging”
  - “Pilot”
  - “National” (Would embody candidate CTEs that are sufficiently mature to propose via rulemaking.)

# Technical Standards Classification Process

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- Process to annually review technical standards and implementation specifications
- Help inform the maturity pathway for standards and specifications for subsequent adoption in regulation.
- Provide direction on what gaps need to be filled to support nationwide electronic exchange.
- Standards/implementation specifications would be classified as:
  - Emerging
  - Pilot
  - National
- Interoperability CTEs would reflect the technical maturity and adoptability of specs that had reached a “national” classification

# Monitoring and Oversight

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- We believe a process to receive and address complaints as well as a process to revoke an NVE's status would need to exist.
- Shared responsibility
- Actors involved in monitoring and oversight of NwHIN governance could include:
  - ONC
  - NwHIN accreditation body and validation bodies
  - Federal agencies including the Federal Trade Commission (FTC) and the HHS Office for Civil Rights (OCR).

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# Questions