



April 3, 2015

Karen DeSalvo, MD, MPH, MSc  
National Coordinator for Health Information Technology  
Acting Assistant Secretary  
Department of Health and Human Services  
200 Independence Ave., S.W. Suite 729-D  
Washington, D.C. 20201

RE: Connecting Health and Care for the Nation: A 10-Year Vision to Achieve  
an Interoperable Health IT Infrastructure

Dear Dr. DeSalvo:

The Cooperative Exchange strongly advocates for EDI standardization and compliance within the healthcare industry. We are committed to promote and advance electronic data exchange for the healthcare industry by improving efficiency, advocacy, and education to industry stakeholders and government entities. Cooperative Exchange supports ONC's efforts to rally all stakeholders within the health industry around a specifically defined healthcare industry interoperability road map.

### **Cooperative Exchange Background**

Cooperative Exchange is the nationally recognized resource and representative of the clearinghouse industry for the media, governmental bodies and other interested parties. The Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability and are a key enabler of this country's interoperability effort.

Cooperative Exchange 25 clearinghouse member companies<sup>1</sup>, represent over 80% of the clearinghouse industry and process annually over 4 billion plus claims representing \$1,1 trillion, from over 750,000 provider organizations, through more than 7,000 payer connections and 1,000 HIT vendors. Combined with our non-profit members (AMA, ASC X12N and UHIN) and Supporting Organizations (Axiom, BancTec and MEA) the Cooperative Exchange ***truly represent the healthcare industry EDI highway infrastructure*** and maintains hundreds of thousands of highways and the majority of the on and off ramp connections across all lines of healthcare business in this country.

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<sup>1</sup> American Medical Association (AMA), Apex EDI, ASC X12N, Availity, LLC, AXIOM Systems, Inc., BancTec, Cerner, ClaimRemedi, Emdeon, eProvider Solutions, Dorado Systems, GE Healthcare, Greenway Health, Health-e-Web, Inc., HDM Corp., InstaMed, Jopari Solutions, Inc., Medical Electronic Attachments (MEA), NextGen Healthcare, OfficeAlly, OptumInsight, PassportHealth, PracticeInsight, RelayHealth, Secure EDI, The SSI Group, Trizetto Provider Solutions, Utah Health Information Exchange (UHIN), WEX, Inc., WorkCompEDI, Xerox EDI Direct, ZirMed ([CLICK HERE](#) for Cooperative Exchange industry resource information)

In that light, following are the Cooperative Exchange responses to the ONC's specific questions:

### General

**1. Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?**

The Roadmap describes critical actions for enabling nationwide interoperability of electronic health information and we agree on the importance of including both administrative and clinical data; however we would recommend ONC address both of these issues simultaneously.

ONC should recognize that the clearinghouse interoperability infrastructure already exist today.

In reviewing the ONC Roadmap, we found that the role of the clearinghouse was a critical missing interoperability component to the plan. Today, the Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of connection points
- Providing **flexible solutions** to accommodate the different levels of stakeholder EDI readiness (low tech to high tech to facilitate adoption)
- Receive and submit both real time and batch transactions
- Support flexible formats to provide interoperability by normalizing disparate data to industry standards
- Actively participates and provides strong representations across all the national standard organization with many of our members holding leadership positions that further strengths our support to facilitate stakeholder interoperability adoption
- Securely manage and move complex data content including administrative and clinical information

The Cooperative Exchange strongly agrees with ONC Roadmap guiding principles as listed on Page 20, one of which is "Build upon the existing health IT infrastructure. Significant investments have been made in health IT across the care delivery system and in other relevant sectors that need to exchange electronic health information with individuals and care providers. To the extent possible, we will encourage stakeholders to build from existing health IT infrastructure, increasing interoperability and functionality as needed."

One key lesson we have learned from industry experience is the need to leverage existing EDI Investments, connectivity, improve end to end workflow automation as well as clear ROI to facilitate stakeholder interoperability adoption. We would encourage additional dialogue between ONC and the Cooperative Exchange members to explore how to leverage the existing interoperability infrastructure to further support stakeholder adoption and improve the healthcare delivery system.

## **2. What, if any, gaps need to be addressed?**

A single healthcare industry interoperability road map that includes both administrative and clinical pathways is critical to the success of the interoperability road map. Clearinghouses have been focused on increasing the efficiency of the transport of both clinical and administrative data and understand the value of a joint road map. Clinical and administrative data are both used to support similar decision making, whether it be medical record documentation transported and used to provide prior authorization approval, support a claim submission or better understand prior treatment of a patient by a treating physician. Clinical and administrative data includes HIPAA identified code sets, such as ICD-9 and ICD-10, HCPCS for multiple reporting purposes that cross boundaries, such as all payer claims databases, population health registries, utilization review reporting to name a few.

The identification of the key data required for both administrative and clinical processes and how to share that information across multiple systems needs to be addressed. Additionally, the placement of this data into automated stakeholder workflows that aid decision making, regardless if administrative or clinical in nature is the first step. One healthcare industry interoperability roadmap will allow all stakeholders to support the effort and advance automation, effectively reducing the need for costly manual workflows.

In addition, the value proposition of data interchange must be more strongly developed with the assistance of stakeholders. Following that stakeholder education conveying the value drivers for data interoperability and the value of accessible medical information made available securely to the appropriate receiver should be a high priority. Clearly communicated return on investment and the implications to the industry of not meeting the associated deadlines is crucial to the success of the interoperability roadmap. This education is needed for all industry stakeholders, including consumers, providers, payers, clearinghouses, and other trading and technical partners.

## **3. Is the timing of specific actions appropriate?**

The Cooperative Exchange would suggest that many of the timelines for implementation are too optimistic. Vendors and clearinghouses need time for product development and testing before those products can be rolled out to other users who must then spend time in implementation and training. ONC needs to realize these practical considerations and include them in timelines as well as take into consideration other existing and or emerging regulations in which there are competing resource issues.

### **3.4. Are the right actors/stakeholders associated with critical actions?**

The list of stakeholders on Page 5 include, "People and organizations that provide health IT capabilities Technology developers for EHR and other health IT, including but not limited to health information exchange (HIE) technology, laboratory information systems, personal health records, pharmacy systems, mobile technology, medical device manufacturers and other technology that provides health IT capabilities and services." **The Cooperative Exchange strongly encourages ONC to add Clearinghouses to this list of organizations as clearinghouses play a key enabler role in the infrastructure framework.**

Clearinghouses have extensive experience transporting administrative and clinical information. In addition, Clearinghouses normalize raw data from transactions into easy to access solutions for all stakeholders. Cooperative Exchange on behalf of its member clearinghouses would welcome an opportunity to assist in the development of a single administrative and clinical roadmap and driving its adoption. By re-tooling existing IT investment, resources and leveraging relationships to streamline administrative simplification and improve access to care.

### **Priority Use Cases**

Cooperative Exchange recommends the following use cases to move the administrative and clinical operability roadmap forward.

- Those who pay for care use standardized transactions and interoperability to acquire data needed to justify payment.
- Payers review clinical documentation for approval of services (prior authorization).
- Payers use integrated data from clinical and administrative sources to determine reimbursement in support of payment reform.
- Payers & Providers should be able to receive notification automatically through the health IT system when a beneficiary is admitted to the hospital.

Automation of the exchange of clinical documentation would reduce manual processes for multiple stakeholders. This will become more significant as the industry shifts to value based payment and other incentives based on quality. Clearinghouses stand ready to serve as the technology enablers to exchange this information between stakeholders of varying technological readiness.

In addition, the following use case should be considered, as notification using DIRECT or other protocols has proven return on investment as showcased at the October WEDI annual meeting. With the movement to value based payment, these patient notification systems are critical to attributed providers within bundled payment models and ACO arrangements.

### **Governance**

- 1. The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?**

Cooperative Exchange on behalf of its member clearinghouses would welcome an opportunity to participate in the governance process assist in the development a single administrative and clinical roadmap and driving its adoption.

ONC must recognize the volunteer workforce is overburdened and spread thin across all of the standard setting, operating rule and related organizations, including S&I initiatives. ONC is encouraged to work with HHS to investigate options to better coordinate the work of the various standard setting bodies,

including ONC, ASC X12, HL7, NUBC, NUCC, CAQH CORE and others related bodies and encourage increased participation by volunteers or funding of support staff.

### **Supportive Business, Cultural, Clinical and Regulatory**

- 1. How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?**

Adoption of clinical record exchange will occur when it is easy to use, incorporated within a streamlined workflow, there is value tied to the action and stakeholders trust the data and security of the transport. In addition, the movement toward value based agreements that include payer incentives for the sharing of clinical information will assist in adoption.

### **Privacy and Security Protections for Health Information**

- 1. What security aspects of RESTful services need to be addressed in a standardized manner?**

The Cooperative Exchange is encouraged by the use of RESTful services supporting exchanges for Healthcare Industry Stakeholders such as payers, providers and facilities and patients. These exchanges should take into consideration the hub model of the clearinghouse. Exchanges should include clinical and administrative data content exchange and have a stable, secure and implementable approach for the services. While pilots have in the past been mainly focused on point to point clinical exchanges, it would be prudent to investigate how to leverage these same protocols for administrative exchanges [real-time/batch] via clearinghouses.

Privacy and Security rules for these types of services will necessitate a review of the current requirements. Cloud based storage, cache memory and minimum retention for virtual storage are a few items not specifically addressed in the most current Privacy and Security rules. Identity Authentication is an area which standardization should work for both clinical and administrative exchanges. The Rules will need to be more inclusive to support the advancing architectures and exchange models which include clearinghouses.

Accreditation, audit and minimum requirements must be made scalable to support the different industry participants. Standardization of the security requirements need to have industry input in order to implement a seamless exchange. Cost for implementation must inherently be a part of the overall privacy and security rule review. Any changes should be supportive of Administrative Simplification in both ease of implementation and cost.

### **Core Technical Standards and Functions**

- 1. Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?**

ONC is encouraged to support and participate in an industry forum (e.g., WEDI) to identify standard industry data needs, such as HEDIS and STARS and develop recommended standard API data pull formats and to encourage the use of these standard APIs data pulls.

The Cooperative Exchange clearinghouse members today support flexible formats including HL7 and stand ready to facilitate data interchange to accommodate new emerging formats such as Fast Healthcare Interoperability Resources (FHIR).

**2. Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?**

In addition, an electronic standard intake process needs to be created that is applicable for all provider settings, including demographics, health insurance information, personal health history, HIPAA attestation.

There needs to be a national standard identifier for all consumers in order to facilitate proper data matching.

**Certification and Testing**

The Cooperative Exchange is pleased to see that ONC recognizes that “Certification and Testing to Support Adoption and Optimization of Health IT Products and Services” is one of the 5 Interoperability Roadmap Building Blocks. Cooperative Exchange members have participated in a variety of accreditation programs such as EHNAC to assure our customers that we meet or exceed industry requirements for standards, privacy, and security.

ONC has stated on page 74 of the roadmap that one of the Learning Health Systems requirements is “Stakeholder assurance that health IT is interoperable: Stakeholders that purchase and use health IT must have a reasonable assurance that what they are purchasing can interoperate with other systems.” While we agree that interoperability is one of the requirements, we would propose that the roadmap go further than just the certification/accreditation and testing of the interoperability standards. The range of functions, ease of use, vendor support and product platforms are all key issues for users of IT products. In addition to “base” certification of standards, we would also recommend that ONC confer and include vendor and user groups to help define best practices for IT products to meet, especially in the realm of interoperability.

The Cooperative Exchange is also pleased to see that the list of critical actions for the certification/accreditation and testing requirements includes a mention of other industry certification/accreditation programs to complement the ONC program. However, Cooperative Exchange entities already face a multitude of existing certification and accreditation programs. It will be important for ONC to recognize and work closely with other certification/accreditation programs to reduce any duplication of effort on the part of stakeholders and to align, as closely as possible, requirements among programs. Cooperative Exchange would recommend that ONC should evaluate ways for entities to

undergo a minimum of certification/accreditation programs to accomplish these goals resulting in reducing the cost of healthcare.

Cooperative Exchange also recommends that ONC reviews and evaluates required versus optional certification/accreditation, and allow entities to choose the certifications/accreditations they wish to achieve. It will be the decision of the users of products to determine what certifications/accreditations they feel are necessary for a product in determining compliance with privacy, security and confidentiality to minimize exposure and risk of a breach or incident. A “one size fits all” approach leads to complex and “over-architected” products which may contain features not necessary to a wide range of users.

We recommend that ONC work closely with certification/accreditation and testing organizations during the standards adoption process. It will be helpful to have certification/accreditation and testing tools available as early as possible in the product development stage so that vendors can assure their products meet the criteria as early as possible.

**1. In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)**

Standard certification and testing protocols should be applied. Relevant use cases should be identified to ensure the C-CDA content can be seamlessly transferred to the end user to meet the intended business need. ONC should work to assure that there are a number of recognized certification bodies, and that certification should be consistent across organizations. Cost is also a consideration and should not be a barrier to achieving certification.

**Measurement**

**1. Does the measurement and evaluation framework cover key areas? What concepts are missing?**

The Cooperative Exchange finds the existing and potential conflicts between numerous emerging mandates are a major concern, as the industry is challenged with implementation, adoption and value realization of these converging mandates. The Cooperative Exchange encourages efforts to reach out to the industry to get input on evaluation criteria to mitigate unnecessary administrative burden due to proposed and or existing mandates that today may not meet industry business needs and or need to be reassessed to ensure industry adoption and proven return on investment.

Measurements for data exchange should be expanded to include those data elements used in the administrative exchanges that cross over to the clinical exchanges. Standard definitions and measurement for evaluation should be similar. It is interesting to note that the line between clinical data and administrative data is being blurred as interoperability moves forward. The Cooperative Exchange has witnessed the clearinghouse model to include clinical data exchanges for administrative purposes. What can be reported is that an “exchange is an exchange” irrespective of the source of the or recipient. A harmonization of the measurement and evaluation for both clinical and administrative

data is the missing concept. A name, date of birth or any one of the common data set elements occur in many exchanges: the question begs why the definition or measurement would be different for the same data for a specific use case. The re-use of good data in any exchange should be the overarching goal.

**2. Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?**

Core measurements should include timeliness, accuracy, conformance and accountability. These measures can be standardized to support the overall exchange of health care data irrespective of immediate use of the data. More often value is being identified when there is a union of clinical and administrative data. The more timely and accurate the data, the more reliable the information. The combination of the information provided will provide the industry with the knowledge that has long been needed to make healthcare accessible and affordable.

The Cooperative Exchange recommends the following evaluation criteria for consideration:

- a) Review and prioritize: Existing, competing and emerging priorities.
- b) Examine opportunities based on the impact on the converged end to end administrative and clinical workflows.
- c) Provide ROI impact analysis, based on:
  - Is there a business need and if so,
  - Business Impact
  - Technical impact
  - Specific stakeholder impact
  - Testing & implementation requirements
  - Testing and implementation cost
  - Time to ROI
  - Stakeholder and Vendor EDI Readiness
  - Pilot Testing Standards and Operating Rules as applicable
- d) Perform post implementation evaluation as applicable Review current process to be able to make changes and/or corrections in a timely matter to mitigate potential negative industry impact.
- e) Create standard benchmarking metrics to measure outcomes, improve business processes and identify ROI results.

**3. Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g., encounter, patient, provider, organization)?**

Each use case is important to the immediate issue at hand. Measurements can be agnostic of the use case to focus on the quality of the data and the ability to achieve interoperability. This method of measurement has been the model of the clearinghouse exchanges. While it is important to know the actors, roles and type of exchanges it is more also important to have interoperability and quality data.



Much of the content and use case issues can be addressed through technical standards and standard implementations. The clinical exchanges have always had standards, but have lagged in the standard implementation or exchange. **The industry should leverage what has been successful in the administrative exchange world and build on already developed infrastructure.**

- 4. What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?**

The Cooperative Exchange believes that clearinghouses could serve as a central collection and management point, and certainly a test bed for measuring data exchange successes. Clearinghouses already have the capacity to measure volumes and accuracy of transaction, rates of exchange among users, and potential cost savings.

- 5. What measurement gaps should be prioritized and addressed quickly?**

There appears to be a gap in measuring the number of key entities that refuse or limit the exchange of healthcare data. State programs, integrated healthcare systems and specialty providers often times are either not included or exclude themselves by using the HIPAA regulations to minimally share data. If the goal is to make the exchanges patient centric in order to facilitate the exchange of information for treatment, payment and operations, then understanding the barriers that are placed by organizations need to be identified so that changes to regulations can be made to either require or allow more exchanges.

- 6. What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?**

In the short run, we can use information from clearinghouses on the number and types of transactions flowing among providers and with health plans. We can also measure how long it takes newer types of transactions to start flowing. Baseline data exists today in clearinghouses.

Sincerely,



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