**Introduction**

DirectTrust, a national non-profit trade association with 130 members dedicated to the establishment, evolution and governance of a national trust framework and operational network for health information exchange, is pleased to submit Comments on the Proposed Interoperability Standards Measurement Framework from the Office of the National Coordinator for Health Information (ONC). The Comments are the product of DirectTrust’s voluntary Clinicians Steering Group, chaired by Steven Lane, MD (Sutter Health) and Holly Miller MD (MedAllies):

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The Comments derive from a lengthy White Paper developed by the Clinicians Steering Group for publication to the HIE community: “Feature and Function Recommendations to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care.” A preview of these Recommendations was presented by Steven Lane MD and Larry Garber MD at the ONC Direct Exchange Workshop on June 9, 2017. The Comments, which discuss metrics, recommend metrics and their prioritization, and answer selected questions posed by ONC, all reflect strong consensus in the Clinicians Steering Group evolved over months of detailed work on this White Paper.

We would welcome the opportunity to answer further questions or contribute in any way to improvement of interoperability facilitated by electronic exchange of health information.

**DirectTrust Clinicians Steering Group**

**Comments on the ONC’s** [**Proposed Interoperability Standards Measurement Framework**](https://www.healthit.gov/sites/default/files/ONCProposedIOStandardsMeasFrameworkREV.pdf)

General Comments:

While the measurement of interoperability standards implementation in IT products and the implementation of these products by customers is necessary, these are not sufficient to support the meaningful exchange of clinical data to improve patient care and population health management. In addition to the proposed scope, we therefore believe that the Interoperability Standards Measurement Framework should address the following items:

1. **The actual exchange of clinical data** utilizing the interoperability standards that are contained in health IT products or used by providers
2. **The utilization of exchanged data** to impact clinical care
3. **The rate of failed or inappropriate exchange** as reflected in the inability to send data or the erroneous sending of data due to inaccurate patient matching between systems

Furthermore, we feel that interoperability rates in general are dramatically improved when processes are automated. We also believe that healthcare IT vendors tend to create functionality and customers tend to implement functionality that specifically address activities and outcomes that are measured and reported. Thus, it is important that the Interoperability Standards Measurement Framework specifically measure the extent to which interoperability processes are automated, and data within Direct messages is reviewed and used for reconciliation.

If HISPs, EHRs and other IT vendors were required to provide standard metrics and reporting tools to their customers, it should not be an undue burden on those customers to report these metrics to ONC or another body designated to collect this data.

1. Customers may install software without training, which may hinder the meaningful use of new capabilities. While clinicians and clinical data analysts may have functionality available to them, the utilization of these tools typically require changes in established workflows, which come only with focused attention on change management including communications, training, support, monitoring and ongoing optimization. Many providers and organizations implement software capabilities in order to satisfy a regulatory requirement with no immediate intention to utilize the functionality beyond a demonstration or pilot group of users. As such, it is critical that the measurement framework allow/require end users to report their actual use of the standards to impact patient care and population health management. While surveys of vendors and healthcare organizations to determine whether implemented standards are useful, they are not a substitute for measuring the exchange that occurs as a result of these implementations. We therefore suggest that the measurement framework include a requirement for end user customers or their organizations to report the actual volume of exchange.

Recommended metrics include:

Level 1 Priority

* # of Direct messages automatically sent
* # of Direct messages automatically received and routed to recipient’s mailbox
* # of Direct messages manually sent and received/routed
* % of reconciliation of PAMI Data in the recipient EHR resulting from Direct message receipt
* # of external providers/organizations with which Direct messages are exchanged
* # of received Direct messages automatically correctly matched to a patient
* # of received Direct messages that were sent in “real time”, i.e. not the result of a batch process
* # and % of active patients impacted by successful direct message document exchange
* # of Problems, Allergies, and Medications received from outside organizations that are reconciled and/or incorporated into the local health record as discrete data (using standardized vocabularies).
* # of Immunizations, Procedures, and Test Results received from outside organizations that are automatically reconciled and/or incorporated into the local health record as discrete data (using standardized vocabularies), and the # that are manually reconciled and/or incorporated into the local health record as discrete data (using standardized vocabularies).

Level 2 priority

* # of automatically, and # of manually, sent and received Cross Community Patient Discovery (XCPD) queries
* % of sent and received XCPD queries resulting in an effective patient match
* # automated releases, and # of manual releases, of C-CDA and other documents in response to document requests from outside organizations
* # of successful downloads of C-CDA and other documents based on document requests (e.g. XCA or FHIR)
* # of successful automated, and # of successful manual, downloads and routing/notification of C-CDA and other documents based on document requests (e.g. XCA or FHIR)
* # and % of active patients impacted by successful document requests
* # and % of active patients participating in the sending/receiving of Direct messages

We urge that all metrics be published widely at least semi-annually, to promote awareness and encourage feedback from communities directly involved.

1. Unfortunately, the exchange of clinical data does not consistently lead to a change in clinical practice or benefit for the patients involved. If received outside data is stored apart from or in a different format than locally generated data, clinicians may not be aware of its existence or may not be able to efficiently review or utilize this data when making clinical decisions for patients.

We therefore urge requirements to document how often received external data is integrated and utilized in local health records in such a way that it can be accessed and used to affect the care provided to patients.

Recommended metrics include:

* # of codified Problems, Allergies, Medications, Immunizations, Procedures, and Laboratory results received from outside organizations that are automatically reconciled and/or incorporated into the local health record, and the # that are manually reconciled and/or incorporated into the local health record.
* # and % of active patients whose care is affected by the incorporation of discrete external data
* # of automatically, and # of manually, received and incorporated into the local health record encounter-specific documents (e.g., procedure reports, discharge summaries, consult, or visit notes)
* # and % of active patients affected by the incorporation of encounter-specific documents
1. It is important to measure missed opportunities/failures of information exchange, including situations where information should have been transmitted but could not be, as well as situations where information may have been transmitted inappropriately.

Specific challenges in this regard include the inability to identify/match records for the same patient in different systems due to variability in demographic data and/or matching algorithms and the problem of maintaining accurate information regarding a patient’s care team in order to know where clinical data should be sent.

Recommended metrics include:
* # and % of messages /documents sent to the inappropriate recipient based on inaccurate information in the sending system, e.g., maintenance of patient’s PCP and other care team membership
* # and % of incoming messages requiring manual intervention to effect patient matching
* # and % of inaccurate patient matches
* # and % of patient record merges and un-merges performed due to inaccurate patient matching
* # and % of patient mismatches that were identified and completely corrected before inaccurate data was viewed within the receiving system and/or released to others
* # of faxed messages received that could have been received via Direct
* # of data pulls because push was not available
* # of referrals and transfers in care where HIE does not occur

Responses to Specific Questions:

1. Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system’s value to stakeholders?
	* *We believe that a voluntary reporting system will be inadequate. Some vendors might choose not to report or might report only specific measures, making it difficult to compare the true capabilities between products. In addition, voluntary reporting will need lead to requiring vendors to have standardized functional capabilities for the interoperability measurements suggested to function uniformly across systems. We therefore recommend that required measurement of interoperability capabilities should be incorporated into future versions of MIPS/MACRA and that the demonstration of successful implementation and meaningful use of these tools be established as a requirement for continued certification of applicable HIT products.*
2. Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?
* *We believe that semi-annual reporting is feasible if vendors are required to incorporate standardized functionality, measurement and reporting tools into their products.*
1. Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?
* *We recommend incorporating clinician input into the selection of the required functionalities and standards that should be monitored.*
1. How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?
* *It will be critical to the success of this program that measures be fully specified so that each vendor utilizes the same definitions. Only this level of specification and consistency will allow clinicians and healthcare organizations to be able to compare vendors’ products and contrast their own performance. Such standardization is the proper role of ONC and could be promulgated through regulation, as customary, to allow for public comment and modification if needed. But standardized definitions are essential.*