

DirectTrust Comments on Medicare Access and CHIP Reauthorization Act of 2016, in Response to Request for Information Regarding Assessing Interoperability for MACRA.

DirectTrust is pleased to offer comments on the subject of interoperability and health information exchange, and on metrics that address the specific populations and aspects of interoperable health information described in section 106(b)(1)(B) of the MACRA, in accordance with the RFI issued by ONC on April 7, 2016.

BACKGROUND: DirectTrust's 142 members are a dynamic community of interoperable health information exchange service providers (HISPs, CAs, and RAs), health IT vendors, and health care organizations of many kinds, organized as a self-governing, not-for-profit industry alliance. DirectTrust and its members are dedicated to the use of interoperable, secure, standards-based health information exchange via the Direct standard, as well as other vendor-agnostic technologies to improve care coordination and reduce health care costs.

DirectTrust originated as the "Rules of the Road" Workgroup chartered under the Direct Project in March of 2011, and is the successor to that Workgroup in both spirit and execution. DirectTrust has carried over from the Direct Project the members' intention of developing a mechanism of industry self-regulation and private sector/governmental collaboration that would be consistent, with and would be guided by, the principles of the Nationwide Privacy and Security Framework and aligned with ONC policies and roadmaps.

From March, 2013 through March, 2015, DirectTrust was the recipient of a cooperative agreement, the DirectTrust Health Information Exchange Governance Project, awarded in association with the Exemplar Health Information Exchange Governance Entities Program of ONC. During these two years, DirectTrust received approximately three hundred and twenty thousand dollars in grant funding. DirectTrust is now financially sustained by a combination of membership dues and network services fees.

DirectTrust members who are accredited Direct exchange service providers, HISPs, have reported quarterly since 2013 on basic measures of interoperability and volumes of Direct exchange, including: the number of health care organizations nationally with whom the

HISPs contract and who are engaged in Direct exchange; the total number of Direct addresses and accounts provisioned at these organizations; and the volume of messages sent and received via Direct exchange across DirectTrust's network of accredited HISPs. DirectTrust members also engage in interoperability testing and report the results of HISP to HISP exchanges via a color-coding system that indicates complete success of an exchange, success with problems, and failure to exchange. These data are basic to tracking the adoption of Direct exchange nationally and for continuously improving the infrastructure both technical and policy-related of the networks for Direct exchange governed by DirectTrust.

As of March 30, 2016, DirectTrust member service providers have provisioned nearly 1.2 million active Direct accounts and addresses in the health care industry, enabling Direct exchange at over 58,000 health care organizations, most of whom access Direct exchange via ONC certified EHR technology. Over 19 million Direct messages were exchanged in the first quarter of 2016 over the DirectTrust network, the great majority taking place between certified EHR technology users in support of transitions of care and care coordination. The Indian Health Services, US Postal Service, Veterans Administration, and the Centers for Medicare and Medicaid Services all have Direct implementations under way to replace mail, fax, and efax communications between these federal agencies and providers in the private sector beginning in 2016. A new DirectTrust program, Partnership for Patients, puts DirectTrust squarely in the flow of health information exchange by consumer/patients. It will enable DirectTrust members to provide patients and consumers with easy and affordable access to Direct exchange accounts and personal Direct addresses for the exchange of personal health information bi-laterally with their care providers over the DirectTrust network. DirectTrust has a strategic objective to significantly accelerate consumer/patient use of Direct messaging and onboarding through one million patient accounts/addresses for Direct by the end of 2017.

INTRODUCTORY COMMENTS: DirectTrust underscores that interoperability measurement is a difficult area of study, beset by entangled complexities. First, interoperability of electronic exchange of clinical information is a relatively new and highly innovative phenomenon in an industry historically dependent on fax, mail, and courier

services for transport of most clinical information between health care providers, their organizations, and their records' keeping systems. The country as a whole is experiencing a significant increase in the numbers of clinical documents, both structured and unstructured files, and various types of summary data, shared via electronic means over centralized and federated networks such as DirectTrust, eHealthExchange, numerous local and regional HIEs and HIOs, through vendor-based proprietary systems of exchange, and also via a very large assortment of one-off connections such as VPNs.

Second, the infrastructure standards that make it possible for these methods of electronic exchange to spread and cross boundaries of both organizational and health IT systems are relatively new, often being adapted in silos (including enterprise and community-based), are still unfamiliar to many providers and their practices, are imperfectly integrated into EHR technologies, and are still unknown and unused by most consumers and patients. Recent surveys indicate that, despite inroads and progress referred to above for Direct exchange over the DirectTrust network, fax and mail predominate for clinical information exchange regardless of the time and cost-saving potential of electronic exchange. This remains true despite the heroic increases in the adoption of computerized systems enabled by Health Information Technology for Economic and Clinical Health (HITECH) and its investment in computerizing the health sector. This lag suggests that measures of electronic interoperability must be examined in comparison to the legacy methods in order to assess meaningful progress in the digital realm.

Third, we must stress that there are many different technologies and methods available that offer completely different types of interoperable health information exchange experiences - for exchanging parties; for dissimilar use cases; for disparate populations of health care professionals. At best, these capabilities may be complementary with one another. For example, Direct messaging is a prototypical “push” exchange wherein one known party sends data and information to another known party. If there is a query for information embedded in a Direct message and or its attachment, Direct normally requires a person/operator to respond to the query by “pushing” information to the querying party (although this work flow is starting to see automation via APIs). eHealthExchange, on the other hand, is a prototypical “query” form of exchange, wherein one known party may query

multiple known and unknown parties for an automated response and retrieval of data and information in document format. FHIR-based APIs represent still another type of “query-based” interoperable exchange, one designed to be automated such that one application can query another application, e.g. an EHR technology, for specified, structured data sets and to enable the queried application to return them to the querying party. It is possible and relatively common for large organizations, e.g. health care delivery systems or health information exchanges, to utilize all these forms of interoperable health information exchange simultaneously for different purposes and use cases.

A fourth complicating factor is clearly noted in the RFI: interoperable health information exchange is composed of multiple, separable technical components. In general, the transport layer and the content or payload are separate components, and exchange must be accounted for separately from use of the information exchanged. For example, Direct exchange involves a secure, identity-validated transport layer that is based upon the commonly used protocols that support encrypted email messages, SMIME/SMTP. Direct is capable of transporting both content embedded in the message body, and as attachments, which may be of any file type including .doc, .pdf, image file types, and structured data such as the CCDA and FHIR. Yet successful transport (in terms of sending, receiving, security, identity protections) does not *by itself* indicate that content or payload transported was useful, appropriate to the use case, accessed by the intended recipient, integrated into the recipient’s EHR and/or workflow, or had a positive impact on the health and wellbeing of the patient whose personal health information was transported. The same applies to FHIR-based APIs used by a party to query data from an EHR. Even though the API worked as intended and the data queried was returned to the querying party, there is no indication of how or when the retrieved data were used in the care delivery process, whether this use was appropriate, or led to a better outcome than might have occurred in the absence of the data exchange.

Finally, while it seems obvious that interoperable health information exchange should enable improvements in health care delivery, it is difficult to prove. It intuitively makes sense that electronic health records should follow a patient wherever they go in the nation, that health care providers should not have to spend valuable time collecting the same information over

and over, or performing the same expensive procedures when sufficient data already exists, and that patient care should not be jeopardized by the failure to share potentially critical information from one health care provider to the next. The importance of these concepts and the value of electronic health records are enshrined in the HITECH and the Patient Protection and Affordable Care Act (ACA).and reflected in subsequent HHS goals, policies and programs. So far, however, this intuition has been demonstrated primarily in small, highly focused efforts (tracking diabetes indicators, for example) or in systems with some control of both provider and consumer/patient behavior (in Kaiser Permanente, another example).

All these complications mean that the state of the art of measurement of interoperability of health information exchange is at a relatively crude and untested level. DirectTrust applauds ONC's intention as expressed in the RFI to better define some basic parameters of interoperable health information exchange, and to promote national agreement on a set that is independent, as is possible, of the technology or methods used. "Starting simple" seems an important principle to guide these efforts, and we believe that ONC takes this position with its intentions stated on page 7 of the RFI that it "seeks to measure the interoperable exchange and use of information by examining the following: electronically sending; receiving; finding (e.g., request or querying); integrating (e.g., incorporating) information received into a patient's medical record; and the subsequent use of information received electronically from outside sources." This approach is consistent with the recognition that at a later date, further research will undoubtedly be needed for more sophisticated, meaningful, and tailored ways to analyze system efficiencies and patient health outcomes that may result from interoperable exchange becoming more widespread and available.

COMMENTS ON PARTICULAR QUESTIONS: Below, we provide comments on questions posed in the RFI, first listing the question, followed by our comment.

Questions 1 and 4 on pages 9 and 10 ask a similar question: "Should the focus of measurement be limited to the use of certified EHR technology? Alternatively should we consider measurement of exchange and use outside of certified EHR technology?" Examples of the latter mentioned in Question 1 include consumers, behavioral health, and long-term care providers who may not use certified EHR technology, but who may be exchange partners under CMS' Medicare and Medicaid EHR Incentive Programs.

We believe that it is important to measure activity by any and all exchange partners, notwithstanding that ONC plans to assess interoperability primarily among “meaningful EHR users.” The reason for our preference is that there are significant numbers of exchange partners outside the population of providers using certified EHR technology, for example SNFs, home health agencies, social service agencies, etc. These exchange partners are growing in number, especially as ACOs take hold, and in many instances have the opportunity to significantly improve care coordination by participating in interoperable exchanges of health information with EHR users. While DirectTrust does not keep track of this statistic, we know from innumerable conversations that physicians, medical practices, hospitals, and health information exchanges (HIEs and HIOs) on the DirectTrust network use Direct messaging to communicate both among themselves and with other persons or entities that are *not* using certified EHR technology at their end. Further examples include: care coordination nurses and staff members, behavioral and mental health provider organizations, dental practices, departments of health, and consumers, patients, and their care givers or health care proxies.

Questions 3 on page 9 and question 5 on page 13 both ask about the adequacy of the set of measures described as “electronically sending, receiving, finding and integrating data from outside sources, and subsequent use of information electronic received from outside sources,” e.g. medication reconciliation. Question 8 on page 16 further asks about potential measures, and asks for ideas regarding “alternative, national-level measures.”

We believe these measures are all useful in determining how widespread interoperable health information exchange is and the extent to which the information is being used “meaningfully.” We believe that *in addition* it would be really useful to have some baseline of understanding about usage of non-electronic and non-interoperable methods currently in place for health information exchange, e.g. fax, e-fax, mail, and courier. These largely paper-based methods of health information exchange remain the predominant ways of moving health information within the health care industry, and are relied upon very heavily in most medical practices and hospitals, in effect competing with electronic messaging and other forms of electronic transport on a daily basis. Based on constant conversations and observations at DirectTrust, reliance upon fax and mail is a source of inertia within many health care organizations and one of the primary reasons that adoption of electronic exchange methods is occurring at a slower than desired pace.

In general, we support the measures listed on page 15 of the RFI, with this additional caveat: exchanges of health information that are being counted are performed according to established and standards-based methodologies that are national in scope, that the exchanges are performed via systems and operations that are highly secure with identity of the parties assured, and that the exchanges take place primarily through the use of certified health IT products and services.

One additional and alternative national-level measure that we believe may be useful involves the use within Direct and the DirectTrust network of what are known as “message disposition notifications,” or MDNs. These acknowledgements are a key aspect of Direct, similar to a fax machine’s confirmation that a fax has been sent successfully. A Processed MDN indicates that a message has been accepted by the receiving HISP and that HISP has accepted responsibility to attempt delivery to the final recipient; this MDN is *always* required. A Dispatched MDN (also known as a Delivery Status Notification, DSN) indicates that final delivery to the application, e.g. an EHR, was successful; this MDN is optional to request, but **mandatory** to return if requested. Receiving the Dispatched MDN does not necessarily mean that the message has been read by the final recipient; there is no acknowledgement serving that purpose at this time. Failure MDNs or Failure Delivery Status Notifications (DSNs) are used to indicate failure of delivery. Knowing the percentage of Direct messages and attachments that included a Dispatched MDN (or a Failure DSN) could help to measure the availability of the information to the receiving clinicians’ IT system and therefore offers a refinement on the question as to whether or not the information has been used in the clinical workflow and/or decision making processes.