The following are prepared remarks submitted by David C. Kibbe, MD MBA, President and CEO of DirectTrust.org, Inc. ("DirectTrust") on behalf of its members and Board of Directors to the Office of the National Coordinator and the HIT Policy Committee in connection with a hearing on ONC's EHR certification program, held at the Washington Plaza Hotel in Washington, DC on May 7, 2014. We thank ONC and the HIT Policy Committee for this opportunity to provide testimony and participate in a panel discussion on “Certification and Accreditation Organizations.”

Introduction – About DirectTrust

DirectTrust is the successor to the Direct Project “Rules of the Road” Workgroup, incorporated in April, 2012, to serve as a forum and governance body for persons and entities engaged in Direct exchange of electronic health information as part of the Nationwide Health Information Network (NwHIN). DirectTrust is organized as a non-profit, competitively neutral, self-regulatory entity with the goal to develop, promote and, as necessary, help enforce the rules and best practices necessary to maintain security and trust within the Direct community, and to foster widespread public confidence in the Direct exchange of health information. DirectTrust is the awardee of a two-year Cooperative Agreement with ONC within the Exemplar HIE Governance Program.

DirectTrust, in partnership with the Electronic Healthcare Network Accreditation Commission (EHNAC), established in February, 2013, an accreditation and audit program for Direct exchange service providers, including Health Information Services Providers (HISPs), Certificate Authorities (CAs), and Registration Authorities, (RAs), the purpose of which is to set a single, national benchmark for the assurance of privacy, security and trust-in-identity controls practiced by known
counter-parties to Direct exchange. EHNAC-DirectTrust accreditation and audit transparently signals a high level of achievement and practice of these controls, thereby permitting voluntary reliance on accreditation and audit to create a network of “scalable trust,” without the need for further one-off legal contracts or single one-to-one connectivity arrangements.

DirectTrust’s membership has grown significantly over the past year, from 40 member organizations to over 125, and participation in the accreditation and audit programs has exceeded our expectations. There are now 47 organizations involved in the process of accreditation, 14 of whom have achieved full accreditation in all three programs for HISP, CA, and RA roles. Another 25 organizations are in what we call “candidate status,” which means they are actively engaged in the self-attestation phase of accreditation and awaiting dates for onsite auditing. Another 8 organizations have applied for accreditation and will move into candidate status this summer.

Perhaps more important than these numbers are the real world effects they are having. Of the accredited and candidate status HISPs, 26 are now participants in the DirectTrust anchor certificate bundle. Distribution of these trust anchors permits subscribers of these HISPs in all 50 states to send and receive Direct messages and attachments with one another, effectively creating 650 individual connections via a network of trusted Direct service providers. This network serves over 5,000 health care organizations and has provisioned nearly 200,000 Direct addresses in the past nine months. With each new HISP whose trust anchor is approved for inclusion in the trust anchor bundle, this network grows exponentially. HISP to HISP interoperability testing is active and ongoing, and the results, which I will return to shortly, are very encouraging.

DirectTrust’s accreditation program is entirely voluntary and the use of accredited Direct service providers by EHR technology vendors and their customers is not a requirement of the federal government for participation in the Meaningful Use programs, as is the case with ONC certification. Another difference between the mission and objectives of DirectTrust accreditation and that of the ONC HIT certification program is that ONC is testing software for compliance with specific functions and capabilities, whereas DirectTrust and EHNAC are testing organizations who use software against a set of standard, policies, and controls that, taken together, aim at assurances for privacy, security, and trust-in-identity.

However, in a de facto manner, the ONC EHR testing and certification program and the EHNAC-DirectTrust accreditation programs have evolved a parallel and highly related relationship in the market for EHRs in 2014 and going forward. All of the major EHR vendors whose products are being certified for the 2014 Edition Certification Criteria as suitable for meeting Stage 2 Meaningful Use objectives and measures are also either themselves DirectTrust accredited HISPs, or are relying on accredited and candidate status HISPs to provide their customers with Direct exchange capability for transitions of care and for view, download, and transmit objectives and measures. This includes the popular EHR technology supplied by Allscripts, Athenahealth, Cerner Corporation, CPSI, eMDs, EPIC, eClinicalWorks, GE Centricity, Greenway, McKesson, Meditech, NextGen, PracticeFusion, RelayHealth, Siemens, and many other less well-known EHR vendors serving smaller markets of providers and hospitals. These parties, along with over 25 state and regional
HIEs operating accredited HISPs, virtually guarantee the ability of the nation’s healthcare providers to achieve widespread interoperability of IT systems via Directed exchange by the end of 2014. At the end of March 2014, these networked HISPs now serve over 5,000 health care organizations and have provisioned nearly 200,000 unique Direct addresses.

The one slide I have brought for you today gives a “snapshot” of the DirectTrust network as of this week. In the short time I have remaining I would like to go over a few highlights of what this matrix of interoperability testing among 26 HISPs shows.

First, note that 650 HISP-to-HISP connections are being tested, that is, each of the 26 HISPs is testing with each of the remaining 25 HISPs. All addresses used are production-level, not from originating from test servers. Second, note the predominance of the green rectangles, which indicates that the sending HISP’s message triggered a processed Message Dispatch Notice (MDN) from the receiving HISP, and the receiving HISP addressee acknowledged receipt of the message and attachment. The small number of red rectangles indicate that the message could not be delivered to the intended recipient Direct address. Yellow rectangles indicate partial success; for example, if an MDN was received but no acknowledgement by a person of receipt of the message.

What we have learned from over three months of continuous testing, during which time 7 new HISPs have been added to the test group, is extensive. However, to summarize our findings:

- Each Direct implementation is based on its own interpretation of the Applicability Statement, so in essence with 26 HISPs we have “26 Reference Implementations.”
- Most red and yellow responses are due to small differences in interpretation of the Applicability Statement.
- Many errors occur related to minor differences in how MDNs are generated or received, e.g. extra spaces, missing fields, etc.
- Variances from the DirectTrust Certificate Profile and DNS hosting irregularities are uncommon but occasional causes of error.

Our current “learnings” from our testing would strongly suggest that ONC and NIST collaborate with DirectTrust members to improve the testing around EHR modular transport via the Direct Protocol at the time of ONC certification, so that “downstream” errors and interruptions in Direct exchange service of the kind we have been experiencing in our tests do not occur.

With very kind regards,

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January 23, 2013
Figure 1 – DirectTrust Interoperability Testing Matrix, with Comments and Legend