April 28, 2014

Office of the National Coordinator for Health Information Technology
Attn: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
Attn: Dr. Karen B. DeSalvo, MD, MPH, MSc
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 7-729D
Washington, D.C. 20201

RE: Comments regarding Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs) and Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria

Dear Secretary Sebelius and Dr. DeSalvo,

The Kansas Health Information Network, Inc. (KHIN) is a provider led health information exchange in Kansas. KHIN welcomes the opportunity to provide comments in response to the Health Information Technology (HIT) Policy Committee's Stage 3 Draft Recommendations that received approval on March 11, 2014 and the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria. KHIN has chosen to send one set of recommendations regarding both to ONC and HHS. The KHIN recommendations cross both MU3 and 2015 EHR Certification Criteria and focus upon key considerations in the establishment of a strong interoperability strategy for the nation and the regulatory framework that will be necessary to support this.

KHIN is a provider led membership organization comprised of 705 member locations including 87 hospitals, 467 provider practices, 42 FQHCs, 46 Community Mental Health Centers, 19 local health departments, 3 substance abuse treatment facilities and 41 other organizations including payors. KHIN uses a hybrid technical architecture to facilitate health information exchange across 15 different EHR vendors through HL7, XDS.b and XCA integrations (see attached summary list). KHIN has 75 different organizations "live" in production sending data to KHIN on a real time basis. This includes 58 hospitals and 194 clinics with access to over 2 million patients.

KHIN aggressively supports our members in meeting their MU2 requirements.
- Besides query based exchange KHIN is a HISP (Health Internet Service Provider) and supports our members in their transitions of care by making DIRECT services available to the disparate organizations where our members refer their patients. Often these are organizations are without an EHR and could not receive the DIRECT messages without the services KHIN provides.

- KHIN facilitates the exchange of public health data by providing the transport layer to our state department of public health and to the Centers for Disease Control (CDC/BioSense). KHIN

began sending syndromic surveillance data to BioSense in November 2012 and has sent over 1.2 million messages from Kansas emergency departments. KHIN also facilities the transport of data from our member organizations to the following other registries;

- o Bi-directional Transmission to the Immunization registry—WebIZ-over 40,000 messages
- o Electronic Lab Reporting—EpiTrax
- o Cancer Registry
- o Infectious Disease Registry—"Other" state registry

- KHIN provides an untethered personal health record (myHealth eRecords) for free to all Kansas patients. Kansas patients can securely message via DIRECT to their providers now and KHIN is actively working to integrate the CCD/CCDA data from the exchange into myHealth eRecords.

- KHIN is one of the first health information exchanges to develop a process and procedures to include behavioral health information in the exchange; including substance abuse information. The methodology adopted by KHIN has been approved by the National Council of Community Mental Health Centers and SAMHSA to meet 42CFR Part 2. The process allows patients to provide consent at the point of care for the viewing of "sensitive" information and allows the data to be available in the event of a medical emergency.

KHIN, as one of the largest health information exchanges in the nation, is uniquely positioned to provide real life feedback on the interoperability challenges that we face on a daily basis and offer specific recommendations. KHIN and our members are committed to working with the ONC, HHS and CMS in solving this problem. As such, we are encouraging all three organizations to develop a shared interoperability strategy that is supported through all of the levers available to the three organizations. We believe it is necessary for an interoperability strategy to be a key component of MU3 and beyond, and all EHR certification criteria starting with the 2015 EHR voluntary standards.

To advance interoperability KHIN recommends the following:
1. Establishment of non-proprietary standards for interfaces to send patient data from the EHR (or other HIT technology such as Picture Archive Communication System (PACS) to HIEs and other business partners as specified by the provider. Certification must ensure that EHR vendors can demonstrate data transport using the standard interfaces.

Considerations:
Lack of established standards for interfaces and data transport has resulted in a proliferation of proprietary interfaces from HIT vendors. Generally, each EHR/HIT vendor has their own interoperability/integration strategy which results in many "flavors" of data transport including HL7 v.2.3.1, HL7 v.4, HL7 v.2.5.1, HL7 v.3, XDS.b,, XCA, XDR, DIRECT and newly emerging web service hubs. Often the strategy includes combinations of the interfaces listed above. This wide variability and the use of proprietary code by HIT vendors has prevented market involvement and driven up interface prices. Some examples of "third party" integration vendors are emerging but access to the proprietary code has prevented these vendors from making much progress. High interface prices with regular "breaking" of the interface when upgrades are taken is one of the largest barriers to interoperability.

An example of this problem is taking place now as eligible hospitals are trying to meet their MU2 requirements. To meet MU2 most hospitals will need at least three HL7 2.5.1 interfaces. One for labs to send LOINC for reportable diseases, one for immunizations and one for syndromic surveillance to send data to the CDC. To meet Transition of Care (TOC) requirements the hospital will need either an XDS.b or XCA interface/connection to the HIE to share the CCD/CCDA or a DIRECT connection via XDR or a proprietary

HISP to send the CCDA in a secure message. The combination of proprietary interfaces required to meet MU2 is expensive and overwhelming to providers who are trying to care for patients.

Transport methods will mature over time and the interface standards will require periodic updating and a process must be put in place to support this. However, arbitrary movement by HIT vendors to adopt a proprietary integration strategy that deviates from the established standards should be prevented through regulation and certification. Vendors that cannot support standard transport options should not receive certification as the siloing of patient data poses a significant patient safety risk.

2. KHIN supports the establishment of data capture requirements that further ensure accurate patient matching within and across health care systems. These should be included in the 2015 EHR voluntary certification requirements and beyond.

   Considerations:
   KHIN members support the inclusion of the unique data sets outlined in the 2015 EHR certification requirements including mother's maiden name and city, state and country of birth. The addition of these data sets to those already gathered by the HIOs will significantly improve patient matching and patient safety.

3. KHN supports the establishment of standards that encourage TOC Interoperability and Cross Vendor Exchange and encourage strict conformance to the CCDA standard template by EHR vendors.

   Considerations:
   Many KHIN members met this requirement by transporting their CCDAs to the KHIN exchange. This allowed the CCDAs to be available at the point of care to any provider with an EHR product that can support a bi-directional exchange via XDS.b or XCA. Unfortunately, many of the CCD/CCDASs were not configured correctly by the EHR vendor. This caused significant problems for KHIN. Allowing flexibility in the configuration of the CCD/CCDA coupled with the lack of stringent certification testing has resulted in many "flavors" of CCD/CCDAs across EHR vendors. This has created a very complex technical challenge for HIE vendors as they attempt to deconstruct the many CCD/CCDA formats and display the data in actionable manner for providers. This has resulted in an unfortunate compromise where most HIE vendors only display the "static" CCD document because they cannot "hard code" to every CCD/CCDA. Providers using the HIE are forced to scroll through multiple CCD/CCDAs to see all of the information that is available for their patient. This is time consuming and increases the chance the critical information will be missed.

4. KHIN supports audit report certification requirements and testing for EHR vendors to provide audit trail information to the HIE/HIO.

   Considerations:
   Patients expect accurate and timely information regarding who has accessed their health information through the exchange. Unfortunately, if a provider is using an EHR that "embeds" the HIE in the EHR (generally an XDS.b or XCA connection) and the EHR does not pass the ATNA (Audit Trail Node Authentication) to the HIE the HIE does not have any documentation of who accessed the patient's information. The inability of HIOs to provide information to patients regarding who has accessed the patient's data through the exchange is unacceptable and will deplete patient trust. EHR certification must ensure that EHR vendors can send the ATNA feed to the HIE.

5. KHIN supports continued requirements to move to standardized medical terminology.

        <u>Considerations:</u>

        The MU2 requirement for hospitals to electronically send reportable lab values in LOINC forced most hospitals to convert their local lab compendiums to LOINC. This change has already made a significant advancement in interoperability as HIOs can now compile and compare lab values across health care organizations. Whenever possible the KHIN members recommend certification requirements that moves the market toward standardized medical naming conventions.

6. KHIN supports the elimination of the 'Complete EHR' definition.

        <u>Considerations:</u> KHIN agrees with ONC's consideration of discontinuing the use of the Complete EHR definition as a regulatory concept beginning with the 2015 Edition EHR certification criteria. The complete EHR requirement forced Kansas health care providers to purchase or possess technology components that they did not need and did not want to use. A good example of this is KHIN is required by Kansas to offer a personal health record for all of our members. This allows patients to have all of their health information in one location, reduces competition among KHIN members for patients viewing their patient portal and encourages all KHIN members to work together to meet their 5% requirement. Unfortunately, many Kansas providers were required to purchase "or possess" the patient portal that was a part of their complete EHR product simply because the EHR product had been certified as "complete". Providers were advised by the vendors that if they did not use all components of the "complete" product they would not meet the MU2 requirements.

7. KHIN supports the inclusion of the Implantable Device List

        <u>Considerations:</u> KHIN supports the need to record and display a patient's implantable device such as the unique device identifier (UDI) to improve the ability to prevent medical errors, improve the ability to respond to recalls, and other important patient safety benefits.

        It is important that this information is shared with health information exchanges. Health information exchanges will play a critical role in locating and informing patients about potential upgrades and health risks.

8. KHIN supports the decoupling of content and transport capabilities for Transitions of Care

        <u>Considerations:</u> Health care providers should have the option of choosing the HISP they want to work with. While some HISPs have a national market footprint others are unique to a specific state or market. KHIN believes that all EHR vendors should be required to support the XDR specifications that allow any HISP to be "embedded" into the EHR product. This will allow competition in the pricing of DIRECT services, reduce provider directory complexities and allow continuity across a market.

        Certification should also ensure that EHR vendors provide the functionality to not only send a DIRECT message with a CCDA attached but they must also be able to receive a DIRECT message and additionally, respond to a DIRECT message without attaching a CCDA. We understand that ONC feels it is not necessary to regulate this functionality as it seems common sense that this will be available. However, our experience is that many EHR vendors build their technology functionality to specifically meet the MU requirements. Thus the sending of a DIRECT message with a CCDA attached is the only functionality available for many EHRs. Thus, we would encourage ONC to require this

functionality so that providers can receive the CCDA from another provider or send a message in response. Without the ability to respond TOC becomes meaningless.

9. KHIN supports the inclusion of Advance Directives in EHR technology but do not support the requirement that EHRs should determine the most recent AD.

> Considerations: We encourage ONC to require EHR functionality that will capture the advanced directive and send this information to the health information exchange. We acknowledge that it is difficult for EHRs to determine the most recent advance directive and instead feel this is the responsibility of the health information exchange. If the AD is captured and transmitted to the health information exchange all available ADs can be provided and the end user can determine the most recent version.

10. KHIN supports voluntary certification for non-meaningful use EHR products specifically in the area of interoperability.

> Considerations: KHIN regularly works with EHR vendors that provide products to "niche" providers. This includes long term care, behavioral health, community developmental disability organizations (CDDO), hospice, independent living centers, pharmacies, occupational, physical and speech language pathologists, etc. These organizations are using EHR products that meet their individual needs. However, this data is mostly siloed and unavailable due to limited EHR interoperability functionality. A limited voluntary certification process that ensures interoperability is essential.
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> KHIN also supports the development and voluntary certification of "packages" designed to provide patient engagement and care coordination. However, these "packages" must be interoperable and allow data sharing across providers. Certification of these "packages" should focus on meeting minimum interoperability standards.

11. KHIN supports flexibility in the creation of public health message content and transport.

> Considerations: KHIN has been successfully transporting syndromic surveillance messages for Kansas hospital emergency departments to the CDC/BioSense since November 2012. KHIN created the message from the data available in the ADT feed and met the specifications required using HL7 v. 2.3.1 and HL7 v. 2.4. When our members began testing for MU2 they were required to purchase the 2.5.1 version from the EHR vendors even though they had been successfully sending the syndromic surveillance messages. This was redundant and expensive. KHIN members support attestation that the public health messages are successfully received and processed by the receiving agency.
>
> KHIN also supports flexibility in the manner in which ambulatory practices submit syndromic surveillance messages. KHIN has been creating SS messages for Kansas ambulatory practices for 18 months and is ready to submit these messages to BioSense when they are ready to receive them. Having messages configured by HIEs or other third party transport organizations is a good alternative to requiring specific HL7 2.5.1 standards.
>
> KHIN members support changing the public health language to clearly indicate that the EHR vendor's responsibility is the creation of the content of the public health message. Current language that includes "transmission" is misleading and implies to some that the EHR vendor must not only create the message but also transport the message. While FAQs are clear that this is not the intent, changing the language would help to clarify the EHR vendor's responsibility.

Lastly, the content of the EHR vendor's public health messages varies considerably in quality and scope. KHIN members would encourage an additional certification requirement that includes testing the message using the NIST standards. If the message cannot pass the NIST standards it is not going to be acceptable to a public health registry.

12. KHIN supports flexibility in the reporting of non-percentage based measures.

Considerations: There are a number of non-percentage based measures, all involving data transport, which will be difficult to measure accurately using an EHR product alone. This includes the transport of the public health measures, VDT if using an untethered patient portal, TOC if using a HISP outside of the EHR product and EHR to EHR interoperability. We do not believe it is feasible or advisable for EHR vendors to attempt to measure data transport. Instead this is the responsibility of health information exchange organizations.

Currently, KHIN provides Certificates of Accomplishment to all KHIN members when they have met a specific data transport measure. For the public health registries the CofA is also signed by the state department of health. This can be used in the event of a MU audit and we believe that this should be part of the certification process proposed below for HIEs.

To further advance interoperability KHIN supports a voluntary certification process for health information exchanges. This process should be developed in a manner similar to the EHR certification process with several companies authorized to certify HIOs. This will allow for competition in certification pricing and value. Tying Meaningful Use requirements to the HIE certification process will encourage and incentivize health information exchange vendors and health information organizations to pursue accreditation. An example of this is the TOC MU2 requirement that allows eHealth Exchange members several options in meeting the measure.

Thank you for the opportunity to provide feedback to the ONC, HHS and CMS. We appreciate and acknowledge the hard work of transforming health care and we pledge our continuing support to advance our shared goal of improving health outcomes by ensuring patient data is available at the point of care.

Sincerely,

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