Notes with ONC on RMES
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Gary: HL7 developed an EHR System FM back in 2003-2004. Later revised and updated to R1 as a full normative standard in 2007. In 2009 advanced this to be an ISO IS 10781. Have a records management and evidentiary support (RMES) functional profile (FM) released in 2009. Nearly all of the RMES functional profile was incorporated into the EHR S FM R2 base model in and now have full standing as a HL7 and ISO standards.

We are now looking to advance the RMES. Tracking the recommendation from the HIT PC to ONC. How should we best proceed with this recommendation. See Halamka -legal Record-HL7 RMES – which is list of recommendations and how to proceed. (Document included in email)

Looks at capture, retain and persist for the legal record and actually focuses on the content as to what is captured and retained. The EHR FM describes how and EHR system management an EHR Record. As we move forward.

Spoke with Jodi Daniels, John Halamka, Karen DiSalvo and ? over the last few years.

REED: There was also dialogue with Kathy Kenyon in an ONC project on "Unintended Consequences" as well as interest in soliciting input from practicing attorneys in addition to Chad, about questions and concerns. This is dialog continued along the same lines through Ms. Kenyon's departure from ONC, prior to which she conveyed "legal record" topics to Mr. Lipinski and facilitated a meeting with him early last year. That discussion now converges with this one..

Gary: What is the role of certification - What is the pickup of the EHR FM standard – is there pick up? The CCHIT program used this as part of the requirements for certification, but in MU, this was not picked up. There has been uptake in international community.

Ms. Anthony: What information do we have about how attorneys are seeing EHRs?

CHAD: What experience have attorneys had? There are still signification challenges. The output for evidentiary purposes is incomplete and unreliable. It is not uncommon for multiple requests for same record from same EHR will produce different information.

From the plaintiff point of view, this may be seen as not only an issue within release of information, but is there really trust with the information being used to treat the patient. The audit trail report – hope for provenance, but there are gaps – even the vendors admit that this does not tell a lot of the detail and cannot drill down to get the information the needed. Very broad brush comments.

There are cases and issues – may need to prove if a certain document existed or was altered at a certain point and time and if unable to prove this, causes reasonable doubt. There is no standard across the systems. We cannot drill down as our audit trail reporting is not designated to do this type of work. Very often cannot explain the audit trail reports. Vendors cannot read their own audit trail reports.

Mike: ONC (?) has looked at auditing systems in which audit systems (point to ASTM standard that it has to be capable of recording – how deep of provenance do we need to see) is the audit on or off, or can it be manipulated.

From a Health IT perspectives – have fields to captures the information, but getting the doc to record is out of scope – but the auditing is more in scope. What fields need to be documents and what fields must be captured, requirements for completion.

Gary: Identify records have record entries that these records have real world and have ability to function different people documenting at different times point of origination, amendment, extracted for exchange. We do have these kinds of things which should be part of the audit log for the entry itself. Audit logs are also identified for viewing and printing – so not necessarily altering the record only.

We can review in detail what the FM currently describes and make sure it still meets the current issues. We do follow the ASTM auditing standard at this time, but worth reviewing this gain.

Reed: Another set of boundaries are in the last version of the CCHIT requirements. These included foundational legal realm requirements such as if a record has been altered it is easy to tell that the record has been altered and what was altered. Since many major vendors previously certified against those requirements, it would be a purposeful area to include. Recent presentation to an insurer's investigations unit noted the common occurrence of records submitted being re-submitted with obvious alterations but no indication that the record had been altered (using same dates, times, and author authentication as the prior version).

Action Items:
Elise would have to discuss within the different offices with ONC.
Mark Knee should be the primary point of contact as far as schedules and get the ONC team up to speed.
Look at auditing within ONC
Education on their side
Potentially connect with CMS on Program integrity leadership who have weighed in on the consequences to future payment models if problems with EHR records authenticity

HL7 Team: Create an action plan: Go through the existing FM to see what is currently in there and look for areas that may be gaps. See what might be a working project. Determine how we would process this as a standard.
We need to identify next steps and review with the ONC group as a way to move forward.
Supply any additional documents to bring this ONC team up to speed.

Target February

EHR reliability assessment tool concept discussed in Orlando and previously in RMES, possible interest also from ONC so will include in February briefing.