

29 May 2015

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National Coordinator for Health Information Technology  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. DeSalvo,

Thank you for the opportunity to comment on the Meaningful Use Stage 3, Health Information Technology Certification Criteria, Base Electronic Health Record Definition, and ONC Health IT Certification Program Modifications.

Our MU3 NPRM comments are offered as a succession of views:

- 1) from the initial perspective of HITECH and Federal HIT Strategic Plan 2009 objectives;
- 2) from compound lessons of MU 1/2; and finally
- 3) from our current sense of where we are as the result of MU 1/2 and where MU3 should take us.

In addition to the comments that follow, please reference CentriHealth comments on the ONC Interoperability Roadmap, submitted 3 April 2015. MU3 builds on the same exchange – and touted “interoperability” – scheme as MU2.

Thank you for your consideration.

Regards,

[submitted electronically]

Gary Dickinson  
Director, Healthcare Standards, CentriHealth  
Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group

## Our MU3 NPRM Perspective – as an EHR/PHR System Developer and Vendor

As a developer/vendor of ambulatory care provider-focused EHR and patient-focused/controlled PHR systems, one might expect us to be ecstatic about another round of Meaningful Use – pumping sales and adoption of our product(s).

In reviewing the MU3 NPRM, we’ve found it especially challenging to offer comments on a proposal that seems intent on driving the EHR Incentive Program forward with little introspection on failures of MU2 and how they should be overcome in the next iteration. Our point of reference starts with the specific and clear objectives of the 2009 HITECH Act (Section 3001(c)(3)(A)):

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“The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to...

“(i) The electronic exchange and use of health information and the enterprise integration of such information.

“(ii) The utilization of an electronic health record for each person in the United States by 2014...”

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As MU2 totters and the era of MU3 unfolds with publication of the NPRM, we find ourselves with the observations enumerated below – starting at the 2009 outset of HITECH/MU, then learning in MU 1/2, then coming to our senses in context of MU3:

#	We find ourselves:	MU3 NPRM Provisions + Related Comments
At the outset of HITECH (2009)...		
1	Expecting to target products to “specific [HITECH and Federal HIT Strategic Plan] objectives”, thus creating EHR/PHR systems intended to fulfill key objectives identified as (i) and (ii) above	[See comments following]
2	<p>Designing system architectures to facilitate “enterprise integration” and the “electronic exchange and use of health information”, enabling integration and ubiquitous interoperability, and encompassing:</p> <ul style="list-style-type: none"> <li>• Individual purposes – as an account of personal health and healthcare</li> <li>• Professional purposes – as an account of actions taken by providers in support of individual health and provision of healthcare</li> <li>• Business purposes – as a an account of operations, processes and services provided</li> <li>• Legal purposes – as evidence of who did what when, which may be attested for purposes of accountability and substantiation (e.g., of claims for payment) and as the legal record for reporting, administrative and legal proceedings</li> </ul>	<ul style="list-style-type: none"> <li>• Enterprise Integration: addressed in part via implementation of an MU-certified enterprise EHR system</li> <li>• Electronic exchange and use: key themes of MU 2/3 – but achievement of true interoperability (ensuring fitness for use/purpose) is elusive</li> <li>• Individual purposes where the individual is the patient: in MU 2/3 mostly limited to view, download and transmit provisions</li> <li>• Professional purposes: provisions for some uses</li> <li>• Business purposes: provisions for some uses</li> <li>• Legal purposes: no provision</li> </ul>

3	<p>Designing systems which are intentionally centered on health data/records of individual persons, facilitating and documenting:</p> <ul style="list-style-type: none"> <li>• Their health/wellness</li> <li>• Their healthcare across all providers</li> <li>• Their activities and interactions with healthcare providers</li> <li>• Past: chronicle of health and healthcare over time</li> <li>• Present: current orders, prescriptions, care plans, activities</li> <li>• Future: planned activities</li> </ul>	<p>Patient-centered system architecture: no provision  Patient-centered record: no provision</p> <p>Instead \$\$\$ Billions spent on provider-focused EHR systems so most patients could end up with a dozen or more records scattered amongst providers</p>
4	<p>Expecting to continue our high level of customer commitment – to both patients and providers – to develop, implement and support systems designed as:</p> <ul style="list-style-type: none"> <li>• Robust, secure and privacy-focused</li> <li>• Identity certain: as to patients, providers, devices, medications, supplies</li> <li>• Intrinsic, active, and ready to facilitate: patient and provider activities, care, interventions, decisions, work flows, deployments/assignments (persons, locations, devices, supplies, time), communications, reminders, alerts and notifications</li> <li>• Accountability and quality-focused: audit-enabled</li> <li>• Chronological evidence: of actions taken to support individual health and provide healthcare</li> <li>• Facilitative of unique provider practice patterns, activities and documentation: locally configurable</li> </ul>	<ul style="list-style-type: none"> <li>• EHR System security and privacy protections: limited provisions</li> <li>• Identity assignment, management, matching: no provision</li> <li>• Individual identity: no provision</li> <li>• Provider identity: limited provision</li> <li>• Device identity: limited to UDI</li> <li>• Medication identity: limited provision</li> <li>• Supply identity: no provision</li> <li>• Workflow management, real-time operational engagement: no provision</li> <li>• Audit: limited to a handful of security, privacy and record management events</li> <li>• Accountability: limited provision</li> <li>• Chronology of health and healthcare activities: limited provision</li> <li>• Tailoring for provider practice and documentation patterns: no provision</li> <li>• Locally configurable: no provision</li> <li>• PHR Systems: no provision</li> </ul>

Learning...		
5	Learning that MU 1/2 requirements consume extensive development, implementation and support resources for providers and vendors alike	Acknowledged but if anything, resource estimates at extreme low end of actual cost of adoption
6	Finding that MU 1/2 requirements are universally applicable to vendor products to ensure we offer a full selection of menu-options, regardless of actual live implementation requirements	Acknowledged as cost to EHR system developer

7	Learning that MU2 (in particular) has offered little allure to EPs (key to our target market), most being fully satiated by MU1 – if they participated at all: typically resolving to a cost/incentive/benefit equation	← Key take-away for MU3 NPRM authors, and a finding/lesson for the Learning Health System
8	Finding that our EPs want systems which are: <ul style="list-style-type: none"> <li>• Ready (available), immediate (real-time) and responsive to their practice</li> <li>• Tightly integrated with their internal patient/work/information flow</li> <li>• Interactive with mobile devices</li> <li>• Configurable to unique practice patterns, activities and documentation</li> </ul> EPs want systems optimized to their use and practice and are largely indifferent to MU 1/2/3 requirements	← Key finding/lesson
9	Learning that our EPs generally don't want/can't digest an inbound avalanche of messages and documents from external systems, patient summaries or otherwise, via pushes (triggers) and pulls (queries), whether from known or unknown sources	← Key finding/lesson
10	Learning that our EPs have daily challenges to discern truth (authenticity) and fitness for use given ongoing issues of data integrity/quality in MU2-required exchange artifacts – typically HL7 v2 messages and CCDAs documents – inbound (received) from multiple disparate EHR systems and other sources: <ul style="list-style-type: none"> <li>• Often containing fragments of health data/record content compiled from multiple origination events, at different points in time, with multiple authors, in multiple clinical contexts</li> <li>• Often without clear and verifiable identity and match-able to known individual(s) or organization(s)</li> <li>• Often without clear and verifiable authorship, signature or signature role (author/originator, witness, verifier/attester, assembler/bundler)</li> <li>• Often lacking evidence of signature binding to particular data/record content</li> <li>• Often lacking evidence of known completeness or explicit designation of known missing elements</li> <li>• Often lacking evidence of who did what when</li> <li>• Often lacking or unclear as to origination, provenance, authenticity</li> <li>• Often lacking evidence of chain of trust, traceability to source</li> <li>• Often lacking evidence of non-alteration, fidelity to source</li> <li>• Often lacking or unclear as to status as original or subsequent update</li> <li>• Often lacking or unclear as to context, consistency, useful classification and</li> </ul>	<ul style="list-style-type: none"> <li>• Fragmentation of content: most notoriously evident in MU 2/3 CCDA patient summaries containing odd fragments and mashups of clinical content</li> <li>• Individual identity assignment, management, matching: no provision</li> <li>• Organization identity assignment, management, matching: no provision</li> <li>• Verifiable authorship, signature, signature role: no provision</li> <li>• Verifiable signature binding to content: no provision</li> <li>• Evidence of completeness (or not): no provision</li> <li>• Evidence of who did what when: no provision</li> <li>• Evidence of origination, provenance, authenticity: no provision</li> <li>• Evidence of chain of trust, traceability: no provision</li> <li>• Evidence of non-alteration (fidelity to source): no provision</li> <li>• Evidence of original/update: no provision</li> <li>• Clinical/business context: no provision</li> <li>• Chronology of health and healthcare activities:</li> </ul>

	<p>comparability</p> <ul style="list-style-type: none"> <li>• Often lacking or without recognizable chronologies and trends</li> <li>• Often lacking or without recognizable relationships between encounters, problems, diagnoses, orders, medications, results, diagnostics, interventions, observations, therapies, care plans, devices</li> <li>• Often improper use of data types, codes, values, classifications, vocabularies</li> <li>• Often transformed/translated at least twice in the course of exchange – from point of origination to point of end use: source internal representation <u>to</u> MU2-required exchange artifact representation <u>to</u> receiver internal representation</li> <li>• Often transformed/translated without carrying alongside source content (such as original text)</li> </ul>	<p>minimal provision</p> <ul style="list-style-type: none"> <li>• Key clinical relationships: no provision</li> <li>• Double transformations: required from/to exchange artifacts (at each exchange instance), often introducing alterations, errors and omissions</li> <li>• Original content carried alongside (to support primary use): no provision</li> </ul>
11	<p>Learning that our EPs must often engage human review of inbound health data/record content from external sources even <u>after</u> algorithmic checks and verifications, which:</p> <ul style="list-style-type: none"> <li>• Must be undertaken by competent clinical provider</li> <li>• Is labor-intensive</li> <li>• Will require more time as inbound volumes increase</li> </ul>	← Key finding/lesson
12	<p>Confirming that our EPs typically don't have time in their daily practice to rummage through an inbound barrage of patient summaries to find data that is properly articulated and comprehensible, clearly trustworthy, timely, context-evident and pertinent to their immediate clinical care of an individual</p>	← Key finding/lesson
13	<p>Learning that our EPs are not comfortable with liabilities/clinical responsibilities of having imported individual clinical summary content that:</p> <ul style="list-style-type: none"> <li>• Has not been reviewed by a competent clinical provider but</li> <li>• Might be found (later) to have relevance to some particular aspect of clinical care, intervention or decision making</li> <li>• Particularly data content that might have favored a (more) positive outcome</li> </ul> <p>Indeed, you don't know what you don't know</p>	← Key finding/lesson
14	<p>Learning that our EPs often segregate inbound health data/record content, refusing to incorporate it within their own "pristine" business/clinical/legal record:</p> <ul style="list-style-type: none"> <li>• For the data integrity/quality reasons cited (see Comments 10-13); and</li> <li>• Given their inability to find/fix corrupt data/record instances</li> </ul>	← Key finding/lesson
15	<p>Learning that our EPs often do not have adequate basis to trust inbound health data/record content for primary use – clinical care, interventions and decision</p>	← Key finding/lesson

	making – given concerns about data quality/integrity and patient safety	
16	Learning that our EPs believe that narrative (free-text) content often allows them to be more pertinent, precise and articulate in clinical documentation: whether or not resulting data/records are fully coded = computable (machine process-able)	← Key finding/lesson
17	Learning that our EPs believe that their narrative content is more likely to convey what they mean/intend than coded content, particularly as: <ul style="list-style-type: none"> <li>• They document facts, findings and observations in the clinical health record</li> <li>• They interact with professional colleagues and consultants</li> <li>• They interact with patients and family members</li> <li>• They attach their health data/records to submissions or substantiations of claim(s) for payment</li> </ul>	← Key finding/lesson
18	Learning that our EPs often find it easier to allow local clinical professionals to access their EHR systems at the front-end (by issuing access credentials and privileges) than by pushing/pulling MU 2-required exchange artifacts between EHR Systems at the back-end: allowing direct access to authentic data content at the source, eliminating double transformations of health data/record content	← Key finding/lesson, as alternative to MU 2/3 exchange artifacts
19	Learning that our EPs don't believe that MU 2 data collection requirements have any practical benefit to their optimum clinical practice, and in fact are burdensome and wasteful of professional time to capture/include in clinical documentation	← Key finding/lesson
20	Learning that our EPs don't generally believe "standards-based" code/value sets, vocabularies, terminologies – be they from HL7, IHTSDO, LOINC, ONC or otherwise – are sufficiently descriptive, comprehensive, granular and factually accurate to be used to competently articulate their clinical facts, findings, observations and other clinical practice information	← Key finding/lesson
21	Finding that our EPs do care about data integrity/quality in terms of: <ul style="list-style-type: none"> <li>• What health information is directed to them</li> <li>• What health information is attributed to them and conveyed (internally and externally) to other professionals, patients and family members</li> </ul>	← Key finding/lesson
22	Finding that our EPs don't feel a warm kinship with MU 1/2/3 or feel satisfied with Washington – via the EHR Incentive Program or otherwise – telling them how to: <ul style="list-style-type: none"> <li>• Practice medicine, provide clinical care</li> <li>• Document and report particulars parameters regarding their practice, operations, performance, care, interventions and decision making</li> <li>• Exchange health information nor frame communication with their peers</li> </ul>	← Key finding/lesson

23	Finding that our EPs almost universally say: make me, my patients and my practice whole – as your FIRST and FOREMOST consideration and objective	← Key finding/lesson (for vendors)
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Coming to Our Senses...		
24	Coming to the sense that the “big” end of the market has become dominated by a few large players (Epic, Cerner, Meditech and others), that MU 1/2 mostly drove “incentivized” provider buyers to these few “safe” choices, that we now face these same players as they dominate geographic markets and have/will set their own standards	A reducibly small set, seems to follow the pattern/history of the British GP system incentive program a few years back, there are other examples
25	Coming to the sense that MU1 froth become the bursting MU2 “bubble” as we witnessed: <ul style="list-style-type: none"> <li>• Dramatic drop in MU2 EHR system certifications</li> <li>• Massive decline in MU2 EP attestations – despite extended deadlines</li> </ul>	The “bubble” burst (at least in part) because a glut of new and unproven EHR systems entered the market to grab initial MU1 incentive \$\$\$: We believe much of this could have been avoided by retaining the 2009 benchmark of EHR system functionality already established by the voluntary CCHIT certification program, a program previously endorsed and funded (in part) by ONC itself and based in part on HL7 EHR System Functional Model Release 1 (recently revised and promoted to ISO/HL7 10781 EHR-S FM Release 2)
26	Coming to a sense that the current EHR Incentive Program should be scrapped forthwith including all remaining vestiges of MU 1/2/3: it has effectively outlived any ability to further motivate EHR/HIT adoption and that any actual bang is from taxpayer buck(s) already expended	← Yes! Yes!
27	Deciding that the next phase (in fact MU3) should be entirely market-based and market-driven, focused on the individual health record, motivated but not mandated by the voice of CMS and ONC	← Yes! Yes!
28	Peering down the chasm and over-viewing the shambled remains of the once MU2 juggernaut, saddled by incentives that weren’t (for EPs) and interoperability that wasn’t (for almost anyone), then conceiving that the MU3 leap – to overarch the chasm – must be spectacular and unassailable by every measure, then realizing that this MU3 NPRM isn’t that vehicle (as noted in previous comments)	Dare we?

EPs = Eligible Professionals