



eHEALTH INITIATIVE

Real Solutions. Better Health.

April 25, 2014

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW.
Washington, DC 20201

RE: Voluntary 2015 Edition Electronic Health Record (EHR) Certification
Criteria; Interoperability Updates and Regulatory Improvements; Proposed
Rule [79 FR 10880]

Dear Secretary Sebelius,

eHealth Initiative (eHI) welcomes this opportunity to provide comments in response to the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule [79 FR 10880] published February 26, 2014.

eHI is an independent, non-profit, multi-stakeholder organization. Its mission is to drive improvements in the quality, safety, and efficiency of healthcare through information and information technology (IT). eHI advocates for the use of health IT that is practical, sustainable, and advances high quality patient care.

eHI has consistently expressed support for the expansion of health information exchange (HIE) and interoperability in prior regulatory comments and position statements and is also now providing comments on the Stage 3 draft recommendations submitted by the Health IT Policy Committee. We believe that the timely exchange of relevant electronic health information is critical to the success of various innovative healthcare initiatives being launched that are part of larger efforts to achieve better coordination and integration of care among stakeholders in the health care system. As such, our comments in this letter are rooted in the belief that programmatic success for the ONC Standards and Certification Program coupled with the EHR Incentive Program (Meaningful Use) will advance the larger health care goals expressed in numerous Medicare, Medicaid and private sector initiatives.

Computerized Provider Order Entry (CPOE) [79FR10886] – eHI supports ONC’s proposal to split the CPOE certification criterion into three separate criteria with each focused on one of the order types (Medications, Laboratory, and Radiology/Imaging).

Eliminate the ‘Complete EHR’ definition [79FR10907] – eHI generally agrees with ONC’s consideration of discontinuing use of the Complete EHR definition as a regulatory concept

beginning with the 2015 Edition EHR certification criteria. At the same time, we encourage ONC to review feedback received from this proposed rule on the benefits as well as the challenges presented by eliminating this concept as a market signal and to gather additional information as needed before finalizing this proposal. For example, some stakeholders may want the simplicity of a single choice for certification and module-only certification may shift responsibility among providers and vendors to ensure that modules work together, and other requirements, such as privacy and security, are in place for the full product. We are uncertain whether this policy change would result in reduced product capabilities relative to minimum requirements necessary for delivering on Meaningful Use and whether it would tend to increase vendor and product fragmentation.

Clinical Decision Support (CDS) [79FR10891] – eHI recommends allowing the Health eDecisions standard more time to mature before being required. We encourage ONC to revisit this standard in preparation for the 2017 edition but, given the timing of the 2017 Edition process, we have concerns about whether this will mature in time for the publication of the rulemaking.

Family Health History [79FR10893] – As both the Health Level Seven (HL7) Pedigree Standard and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) standard have existing limitations, we encourage further refinement before considering a single standard. We believe the goal should remain finding the best standard to utilize in support of interoperable exchange within the Consolidated-Clinical Document Architecture (C-CDA) documents.

Implantable Device List [79FR10894] – eHI 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.

Transitions of Care [79FR10896] – eHI supports ONC’s proposal to decouple and separately test and certify the “Content” capabilities and the “Transport” capabilities for the Transitions of Care requirement. We urge ONC to consider, however, the maturity of the “Edge Protocols” and its ability to support the requirements defined within the proposed rule.

More frequent rulemaking [79FR10881] – eHI appreciates ONC’s continued consideration regarding the level of effort exerted within the health IT industry to prepare for and implement certification criteria. We also appreciate ONC’s proposals to leverage EHRs to accelerate achievement of better health outcomes for patients across the nation. Publishing the proposed Voluntary 2015 Edition EHR Certification Criteria, especially recommendations for 2017, enables stakeholders to see ONC’s planned expectations and approach towards continued certification of EHR products.

At the same time, we are not convinced that the increased and more frequent cycles of certification and standards criteria are the best way to provide more insight and enhanced implementation timing for providers, vendors, and other industry stakeholders. Rather we

are concerned that the opposite may occur and the timing of publications and expected use, especially by other federal and private sector programs will not provide industry stakeholders enough time to develop, test, implement, and utilize the more frequent changes. However, nothing should impede ONC's publication of technical corrections that addresses errors or provides further clarity for prior rulemaking.

The proposal to increase the pace of rulemaking may also create an environment whereby immature standards are proposed for implementation to support a desired function. Rather, eHI recommends that ONC balance the maturity of standards that support a requirement with the provider use effort, development effort required, and patient benefit as the Health IT Policy Committee addressed for Meaningful Use Stage 3 recommendations.

Voluntary 2015 Edition – The stated “voluntary” nature of these rules could, in fact, shift to one of de facto requirements as they become mandated by federal and private sector programs and other stakeholders other than the EHR Incentive Program, as has been envisioned explicitly by ONC. The desire for more frequent certification should certainly be tempered with consideration of how it could potentially increase burden on providers, hospitals and other industry stakeholders.

Additional Considerations – Based on the rich and diverse expertise and perspectives among eHI's multi-stakeholder membership, we offer specific additional areas for ONC consideration:

Advance Directives [79FR10894] – We encourage ONC to engage in further review regarding advance directives (AD) certification criteria and evaluate the ability of EHRs to link to or access instructions for finding the most recent version of an AD. Also, current certification criteria should require all EHRs the ability to capture this information regardless of the patient's age, which may be appropriate in many instances regardless of specific meaningful use requirements.

Patient Matching [79FR10899] – eHI supports ONC's proposal to take steps in improving patient matching capabilities and encourage consideration of data elements such as place of birth, address or phone number, natal sex, or mother's maiden name. We also support ONC's consideration of addressing the very critical issue of duplicate patient records and quality of a patient's health information which imposes a patient safety risk as well as other issues that impact a provider's ability to treat a patient across the care continuum.

At the same time, we believe these requirements are premature for a 2015 context. For example, not all of these data elements are currently captured in EHRs and within the specified formats. We encourage more evaluation as ONC moves this forward.

Clinical Quality Measures [79FR10902] – eHI encourages ONC to conduct further evaluation of the Health Quality Measures Format Release 2 (HQMF R2) and its ability to

support clinical quality measurement. Because this standard was just released in late 2013, we believe maturation is necessary before including it as a provision within ONC's regulatory framework. We also believe ONC should conduct further analysis and provide evidence that the data is being captured and reported accurately.

Two-Factor Authentication [79FR10904] – Intended to support security and access to healthcare data, this functionality presents several challenges to implementation and use. Several issues to consider are that providers often work at multiple facilities which would require them to potentially carry several devices; large scale implementations to thousands of staff, and financial resources required to deploy such functionality is significant. We encourage and support continued evaluation and development of this technology to support the unique needs of a healthcare environment.

View, Download, and Transmit (VDT) to Third Party [79FR10906] – We support ONC's clarification of the introductory text to allow for patients and their authorized representative to conduct VDT.

Decoupling of Meaningful Use and EHR Certification [79FR10906] – As stated above, we appreciate earlier notice about likely certification directions but, at the same time, are not convinced that the certification model used by ONC should be broadly expanded beyond its primary focus on the meaningful use program, which had been a critical guiding principle adopted by the Health IT Policy Committee. We are not convinced that ONC and the certification bodies have sufficient resources to support expansion given current certification challenges (such as immature standards) and are also not convinced that the certification model will add sufficient value relative to normal market forces to warrant likely additional costs borne by providers, vendors, and other stakeholders.

We do support the proposed process for non-meaningful use relevant software to be certified to applicable criteria, especially for interoperability with the use of mature standards that have been successful in actual implementation, and to be able to do so without needing to certify for meaningful use measurement.

Secure Messaging [79FR10908] – We suggest ONC consider adding to the 2015 Edition the ability to allow for a patient's authorized representative to send and receive secure messages on the patient's behalf, similar to the VDT criterion, to the extent that such a capability is not part of the current requirement. This is similar to the recommendations the Health IT Policy Committee submitted for Meaningful Use Stage 3.

Conclusion

eHI is pleased with the progress of implementation and use of EHRs through support provided by HHS. With ONC and CMS' continued engagement and outreach with health IT stakeholders to inform, develop and mature their use, we anticipate continued improvements with EHR interoperability and exchange of health information, alignment of technology with policy, quality measurement initiatives, continued evaluation of patient

engagement, and program flexibility to advance high quality patient care. eHI appreciates the opportunity to provide comments on the Voluntary 2015 EHR Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,



Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative