eHEALTH INITIATIVE
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May 30, 2014

Office of the National Coordinator for Health Information Technology
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: *HIT Policy Committee: Recommendations regarding Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)*

Dear Dr. DeSalvo,

eHealth Initiative (eHI) welcomes this 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.

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 IT. eHI advocates for the use of health IT that is practical, sustainable, and advances high quality patient care.

We want to thank the HIT Policy Committee for its work on Meaningful Use (MU) Stage 3 over many months and for its recent work to increase the focus of this proposal to Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS). We appreciate consideration of such factors as interoperability, which was identified as a major priority as well as provider use effort, standards maturity, and development burden and patient needs, the latter of which affects all stakeholders. As such, our comments in this letter are rooted in the belief that programmatic success for the MU will advance the larger health care goals expressed in numerous Medicare, Medicaid and private sector initiatives.

General Comments

This section conveys overarching comments we believe are critical to successfully advancing the MU Program into Stage 3 and beyond to improve health outcomes. We address the following subjects:

- Strengthen and increase emphasis on interoperability
  - Build on and deepen use of what has been implemented in Stages 1 and 2, with selective additions to enhance the use and robustness of interoperability
- Learn from and integrate experiences from Stage 1 and Stage 2
- Innovative technologies to support new care delivery and payment models
- Align policy with health IT stakeholder technical and implementation capacity
- Improved quality measurement and reporting initiatives
- Increased patient engagement

- Flexibility in regulation and timing to support participation

Strengthen and increase emphasis on interoperability
The increased emphasis on interoperability within Stage 2 represented a significant step forward from the Stage 1 foundation and should receive additional emphasis for Stage 3, including meaningful use objectives, certification criteria, and broader CMS and ONC programmatic efforts. The MU program serves as one of many tools that promote and support the continuum of health IT transformation and should not stop at just MU. Interoperability serves as a foundation for successful exchange of information that supports care coordination, patient engagement, and public health reporting.

eHI applauds the focus in Stage 2 toward expanded use of standards-based electronic exchange of summaries of care between providers to improve care coordination while reducing health disparities. In its current state, the nation's health IT infrastructure, despite substantial federal efforts and much progress, is immature relative to what is needed to fully support the robust exchange of health information.

An increasingly robust infrastructure is imperative to support current and future expectations for health information exchange and interoperability in Stages 2 and 3. In its current state, the nationwide health IT infrastructure cannot support increasing and more complex exchange requirements that are expected for Stage 3 and beyond. We believe resources and focus should be placed upon usability of the technology that has been used for exchange and generally in health IT implemented and learn what has been successful in Stage 2 and address areas that served as barriers to its intended purpose thus causing undue burden on providers.

Recommendation: In order to maximize benefits for patients, providers, consumers, and public health, we urge ONC and CMS to establish interoperability as the primary Stage 3 operational focus, in terms of meaningful use objectives, certification criteria, and broader CMS and ONC programmatic efforts. CMS and ONC should build on and enhance Stage 2 meaningful use objectives and standards-based electronic health record (EHR) capabilities that serve to improve the current health IT infrastructure and usability for providers.

Learn from and Integrate Experiences from Stage 1 and Stage 2
We urge CMS and ONC to take measured steps to learn from and integrate experiences shared by providers, hospitals, EHR vendors and Health Information Exchanges (HIEs) that have been actively participating and engaged in meeting requirements for Stage 1 and Stage 2. We recognize that meeting the requirements to become a meaningful user of electronic health records is an effort that challenges everyone involved and the program needs to develop a cadence and level of effort that enables participants an opportunity to reach attainable, yet challenging goals.

Recommendation: The scope and timing of Stage 3 should be informed by the Stage 2 experiences of providers, patients, vendors, and HIEs.

Innovative technologies to support new care delivery and payment models
Based on our assessment of the evolving health IT environment, we also emphasize that new and emerging technologies that enable value-based payments and accountable care

should advance in an innovative manner. The meaningful use program and its supporting standards and certification requirements as a minimum or rather, baseline that serves as a foundation from which innovation can develop. We should emphasize the development of infrastructure, such as standards and quality measurements, in support of payment and delivery reform initiatives, while allowing emerging solutions opportunity to mature.

Recommendation: In developing Stage 3 meaningful use objectives and certification criteria, do not seek to include new or evolving functionalities or technologies needed to support new payment and delivery models beyond those that would typically be found in an EHR, letting the market identify which functions are needed and how they should evolve.

Align policy with health IT stakeholder technical and implementation capacity

The rollout and implementation of Stages 1 and 2 of the Meaningful Use Program have challenged stakeholders to learn from and process their experiences and inform the changes that are required to successfully support the Core and Menu objectives, Clinical Quality Measures (CQMs) and the ONC certification standards and certification requirements. As an industry we also have much to learn about the data that are being collected and analyzed on the retention and drop-out rates of the program participants. Such information could serve as the basis for a continuous learning environment to better understand the challenges that patients, providers and hospitals have experienced, some of which are evidenced in minimal participation in attestations to date.

Recommendation: As Stage 3 is developed, establish opportunities to learn from Stages 1 and 2 and for health IT policies to enable providers, vendors, and consumers to adapt to a variety of regulatory and market requirements over the next several years.

Improved quality measurement and reporting initiatives

eHI urges ONC and CMS to accelerate the work of identification, field testing, and refinement of clinical quality measure (CQM) electronic specifications that can be readily implemented by EHRs and support both the current and future requirements of meaningful use and new payment and delivery models. Building upon the foundation developed by Stage 1 and Stage 2, CMS and ONC should continue to invest in quality measure harmonization across programs, health IT infrastructure, and mature standards-based exchange of health information. This process should incorporate the allowable time needed for establishing the necessary standards, field testing, and collaboration among measure developers, providers, vendors, and other end-users during the measure development process.

Recommendation: Enable an informed and consistent approach, allowing for development and/or identification, field testing, and refinement of CQM electronic specifications to support current and future requirements for Stage 3. Given all of these considerations, we urge CMS to consider finalizing a more focused set of measures chosen for Stage 3 and to harmonize eCQM definitions, reporting requirements and timelines, across federal, state, and private sector programs.

Increased patient engagement

eHI applauds ONC's and CMS's continued focus on increasing and encouraging patient engagement. Patient engagement is a prominent goal of the Meaningful Use program and we cannot achieve the Stage 3 goal of improving health outcomes without including patients

and their caregivers in their own health and care. Engaged patients are more active in managing their care, benefiting providers, patients, and the healthcare system as a whole. Patients are willing and able to partner with providers and as Stage 3 criteria are developed, it is vital that criteria that facilitate patient engagement are made more robust. Electronic access to health information and the ability to easily communicate with providers offers patients the information and tools they need to be active partners in their health and care. However, patient access to health information must be meaningful and useful.

Recommendation: Maintain patient engagement as a key element of MU, and in Stage 3 build on the requirements and capabilities established in Stage 2.

Flexibility in regulation and timing to support participation

It also is essential that we take advantage of the opportunity that we have to prevent timing challenges that were experienced with Stage 1 and 2. A detailed focus and constrained scope will help meet other essential policy goals, including:

- Allow at least 18 months before a new stage of meaningful use takes effect from not only the release of Final Rules for each new stage of meaningful use but also the final versions of all associated provider and developer specifications, including certification test methods and tools and quality measure specifications.

- Ensure thorough quality assurance prior to release of quality measures, the certification test tools, and associated test data and methods.

- Establish a 90-day or quarter reporting period for the first year of each new stage of meaningful use for all providers, as was done for Stage 2, allowing deployment of the new versions to be scheduled during the first year of a new stage.

- Finally, we urge early, active, and real consultation with industry stakeholders on development of Stage 3 meaningful use objectives, certification criteria, and test methods and tools. This would also include a formal process to assess usability implications of specific new or revised objectives, measures, and certification criteria.

Beyond initial implementation of Stage 3 and consistent with what HITECH permits and as CMS has outlined its intention, we suggest that any subsequent revisions to MU and certification focus on maintenance changes needed to keep certification and meaningful use requirements current with standards and leverage emerging technology.

Recommendations:

- Allow for appropriate timing between final rule and technical specification publication and when providers must be using the applicable certified EHR technology for meaningful use purposes or similar government programs.
- Beyond initial implementation of Stage 3 allow health IT stakeholders the opportunity to adjust to significant EHR functional requirements and reporting and allow for the market to address any unmet needs.

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:

- **Reminders**
  - The HIT Policy Committee recommended the removal of Reminders as a distinct meaningful use objective and measure, based on its desire to focus and its expectation that this functionality would remain in certified EHRs even if no longer a meaningful use objective. Reminders are an important EHR functionality, especially for patients with chronic conditions who may require complicated drug programs and for whom EHR-generated reminders would serve them well in keeping them on their schedule. We encourage ONC and CMS to evaluate the potential desirability of retaining this meaningful use objective and/or its associated certification criterion, considering the benefits as well as the costs and to solicit comment on its retention or elimination in the notice of proposed rulemaking for MU Stage 3.

- **View online/Download/Transmit (VDT)**
  - We support ONC's clarification of the introductory text to allow for patients and their authorized representative to conduct VDT as outlined in the 2015 Edition proposed regulation.

- **Care planning – advance directive**
  - 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.
  - We also encourage ONC to assess how HIEs can support this requirement.

- **Demographics/patient information**
  - eHI members generally support the proposal to add certification criteria for capture of sexual orientation, gender identity, and disability status as important to improving patient care and health outcomes and urge that CMS and ONC seek comments on such an addition in the Stage 3/2017 Edition proposed rules.
  - eHI members agree with the HIT Policy Committee that ONC and CMS should consider a transition from OMB to the Department of Health and Human Services (HHS) standards when capturing race/ethnicity data, as HHS standards are more granular and capture information important to patient health outcomes. This evidence-based consideration should weigh the benefits against potential costs and burden.

- **Clinical decision support**
  - eHI members are very supportive of a continued focus on clinical decision support in Stage 3 as well as the proposed revision to the meaningful use objective for this item.

- **Visit summary**
  - Visit summaries provided to patients after a visit are an extremely important meaningful use criterion and should be retained. We support the need for "relevant, actionable information, and instructions" but applying these concepts to the actual meaningful use measure could pose a measurement and audit challenge.

- **Order tracking**
  - eHI members are concerned about the high provider and vendor burdens and costs associated with this proposed item. They suggest that, if retained, the focus should be substantially narrowed to emphasize closing the referral loop and to eliminate required capabilities regarding order tracking.

- **Patient generated health data**
  - eHI members see substantial value in addition of patient generated health data to EHRs. We generally applaud the approach proposed by the HIT Policy Committee; especially with respect to enabling provider discretion on how these data are received and to use Stage 2 secure messaging capabilities for receipt as well as to allow credit for data received via interfaces with patient monitors and similar devices. We urge ONC to continue to evaluate the need for creating additional certification criteria for this item that could stifle innovation or establish suboptimal workflows.

- **Notifications**
  - This proposed new meaningful use objective and associated certification criterion could enable important information but, as recognized by the HIT Policy Committee, such functionality should not be expected to be included in EHRs as a general approach. We believe this functionality will evolve to one the is desired by providers who will in turn provide notifications given evolving delivery system incentives without the need for this to be a meaningful use objective or to have functionality constrained or dictated by certification.

Conclusion

eHI is pleased with the well documented progress of expanded implementation and use of EHRs, which has been enabled, in important respects, through HITECH provisions as implemented by the Department of Health and Human Services, most notably the EHR incentive program. Through ONC and CMS' continued engagement and outreach with health IT stakeholders to inform, develop and mature the MU Program, 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 Draft Stage 3 Recommendations. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative