eHEALTH INITIATIVE
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February 25, 2011

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary Switzer Building
330 C Street SW, Suite 1200
Washington, DC 20201
Attention: Joshua Seidman, Ph.D

Submitted electronically at http://www.regulations.gov

Re: Health Information Technology Policy Committee Meaningful Use Workgroup Request for Comments Regarding Stage 2 Meaningful Use

Dear Dr. Seidman,

eHealth Initiative welcomes this opportunity to provide comments on the preliminary recommendations for Stage 2 Meaningful Use (MU) objectives and other issues considered by the Workgroup.

eHealth Initiative (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 information technology (HIT) that is practical, sustainable and addresses stakeholder needs, particularly those of patients. We have attached a list of our members for your information.

eHI applauds the work of the Health Information Technology Policy Committee (HITPC) Meaningful Use Workgroup to develop recommendations within four of the five health outcome policy priority areas. We commend your efforts to revisit the long-term vision of Meaningful Use to determine the steps that are appropriate, reasonable and necessary for continued progress. eHealth Initiative support the commitment of the Office of the National Coordinator (ONC) to include health information exchange (HIE) as a key goal in Stage 2. The objectives, measures, certification criteria and standards in Stage 1 provide the foundation for robust health information exchange. Encouraging greater and deeper use of health information exchange is essential to supporting the goals of Meaningful Use, which aim to create a quality-focused, patient-centered health system.

The comments below were developed through an extensive multi-stakeholder consensus process. Several factors influenced our response. We share these with you to provide context for the comments that follow:

1. Timing of Meaningful Use
It is vital that ONC, in conjunction with the Centers for Medicare and Medicaid Services (CMS), address the issue of inconsistent timelines for the Meaningful Use Stage 2 regulatory process and the start of Meaningful Use Stage 2. The time required to assure Stage 2 readiness by all parties necessitates adequate time to develop, implement and test new functionality by all participants. This will encourage incentive program participation and increase the likelihood of achievement of program goals. Moreover, the current Meaningful

Use Stage 2 regulatory timeline provides an inadequate amount of time for eligible hospitals to follow an implementation and testing schedule. A rushed process could potentially affect patient care. We respectfully request that a statement of guidance from ONC, in conjunction with CMS, is published expeditiously on this issue of coordination of the timelines.

2. Learning from Meaningful Use Stage 1
As the process of developing Stage 2 comments progresses, it is important to incorporate the early evidence from Stage 1 implementation, including the number and type of eligible professionals (EPs) and eligible hospitals (EHs) that have registered, attested, and received incentive payments under the Electronic Health Records (EHR) Incentive Programs. This evidence is crucial in determining whether Stage 2 recommendations represent a stepping stone or a large leap. Any increase in the number of objectives or the threshold of Stage 1 measures should be informed by experience with the current set of objectives. In addition, proposed Stage 2 objectives and measures should be viewed in their totality as they move through the HIT Policy Committee, and when ONC reviews processes in terms of their ability to provide true incentives that balance rigor with feasibility and provider burden.

3. Concurrent healthcare regulatory requirements
The concurrent industry-wide requirements and work streams could greatly affect EPs and EHs attempting to qualify for Meaningful Use incentive payments or those working to support EPs and EHs. Concurrent healthcare regulatory requirements include: the e-quality measure development process; the Medicare pay-for-performance programs; ICD-10 implementation; the Institute of Medicine Patient Safety study and recommendations; medical home regulations as well as the accountable care organization NPRM; and potentially the recommendations from the PCAST Report Workgroup.

4. Ease of use of eMeasures
As criteria and measures are defined, it is important to evaluate the extent to which they can be efficiently and accurately measured and reported, uniformly, by providers with minimal reporting burden. Simple measures should be preferred and qualifications on objectives that require complex measurement processes (such as requiring providers to first define their primary referral network in order to measure a Meaningful Use objective) should be avoided.

5. Applicability of objectives and measures to all EPs and EHs
The emphasis on primary care provider or medical home measures in most requirements poses challenges of applicability to a broader set of physicians, health professionals and hospitals that are qualified to be EPs and EHs. The objectives and measures need to be applicable across a wide range of EPs and EHs.

6. Prioritize interoperability and support for quality analysis
The recommendations should prioritize interoperability and support for quality analysis, in order to improve patient care.

7. Standards identification and development must move in tandem with Meaningful Use
Functionality standards for some of the newer proposed objectives are lacking. This deficit will hinder the ability of these or later recommendations to be operationalized. It is important that standards are in place for the objectives included within Stage 2. In the

absence of this clarity, the degree of variation will remain an inhibitor to program success. Where there are multiple standards, please clarify which standard is applicable. In the absence of standards, the HITPC recommendations should direct the HIT Standards Committee to spur the development of the needed standard, where a standard is feasible and applicable, on an expedited basis.

8. Administrative simplification
Administrative simplification provisions should not be included in Meaningful Use, but should be advanced through other regulatory processes.

9. Additional work needed in exchange of laboratory data
HHS should continue to work on the interaction of Clinical Laboratory Improvement Amendments (CLIA) with state laws vis-a-vis the requirements to disclose lab data to patients. There may be restrictions in certain instances that prohibit the recommendation's intended disclosure. The absence of a definition of "structured" data may result in laboratory tests that appear binary (a patient does or doesn't have a condition), however are not. Oversimplifying the requirements for reporting laboratory results could create the potential for patient harm.

10. Treatment of new objectives as required
Careful consideration should be given to placing new objectives for Stage 2 in a menu set or a core set. The totality of an objective, whether new or old, core or menu, should be considered in the process of determining the final objectives and their associated measures. Additionally, some requirements for Stage 2 may precede results from pilots and demonstration projects led by the Center for Medicare and Medicaid Innovation, and the added insight from that work could improve upon an objective.

11. Apply the principle of parsimony in consideration of new objectives
The principle of parsimony should be followed as you consider increasing the number of objectives, with a general focus in Stage 2 on building on Stage 1 electronic health record (EHR) capabilities and Stage 1 objectives and measures.

Comments on Proposed Objectives and Measures for Stage 2

Improve Quality, Safety, Efficiency, and Reducing Health Disparities

eHI supports many of the proposed recommendations set forth by the Workgroup, including the following:

1. Continuing Stage 1 measures – We agree with the proposal to keep in place current Stage 1 measures for the objectives to maintain problem list, active medication list and medication allergy list.
2. Increased Stage 1 thresholds – We agree, in general, that the objectives related to the recording of patient information should be increased from their current threshold, although in some cases the proposed thresholds may be too challenging.
3. Menu to core transition – We agree in principle with the proposed changes to move Stage 1 menu objectives into Stage 2 core objectives.
4. Computerized physician order entry (CPOE) – We agree with the proposed approach to add lab and radiology orders for Stage 2.

5. New Stage 2 objectives – We agree in principle with the objectives for the recording of electronic notes by eligible providers and hospitals as well as tracking medication orders through electronic medication administration recording (EMAR).

In some objectives, eHI urges additional clarification or definitions. There are many new terms and descriptions proposed for Stage 2 criteria that have yet to be clearly defined and/or have applicable standards assigned to them. These include:

1. CPOE – We would like a clearer definition of "licensed professional" as well as clarification on what "transmitted electronically" explicitly means.
2. Drug-drug/drug-allergy interaction checks – We are concerned with the wording of "appropriate evidence-based interactions," specifically with regards to who is determining the appropriateness of the alert.
3. Clinical decision support – We would like clarification on what "certification" means, specifically what the certification process would entail. There are also additional comments for this objective below.
4. Record existence of an advance directive – As this objective is proposed to become mandatory for both eligible providers and hospitals, we would like to have standards defined for advance directives.
5. Incorporate lab results as structure data – We would like clarification on the term "where available," specifically on who determines this and how it is determined. In addition, there is currently no definition of what "structured" lab data is and we would like a set definition for this as well.
6. Send patient reminders – We would like "active patients" to be clearly defined and clarification on how this objective is to be measured.
7. Electronic notes – We seek clarification on how an "electronic note" should be defined and what standards will be ascribed to it. While we agree that it is important to incorporate electronic notes as part of the medical record, there are many details that need to be clarified and defined.
8. Electronic medication administration recording (EMAR) – We would like clarification on "EMAR," specifically if this means bar coding or another electronic tracking method.

Challenging thresholds: eHI recognizes the intent of the Workgroup for Stage 2 to be a stepping stone, but we urge ONC and CMS to consider feasibility when setting thresholds. These include:

1. E-prescribing – Particularly as eligible hospitals are proposed to be included for e-prescribing, this new threshold might be too challenging for Stage 2.
2. CPOE – We are concerned that the proposed increase in threshold might be too challenging for Stage 2 given the addition of both lab and radiology orders.

Applicability to all providers:
There are several objectives, including the recording of an advance directive and smoking status, where we feel that it is not applicable to all eligible providers. eHI would like to suggest that exclusions be allowed for specialists in these objectives, which are most applicable to primary care providers.

eHI is concerned about the timeline of development and readiness for certain objectives, specifically:

1. Report clinical quality measures (CQM) electronically – We agree with the aligning of recommendations on CQM with CMS and suggest careful collaboration between the Quality Measures Workgroup and the Meaningful Use Workgroup to ensure that the criteria and the associated measures being developed are aligned. Also, we are concerned about the timeline of development for vendors, providers and hospitals.
2. Drug-drug/drug-allergy interaction checks – We urge ONC and CMS to carefully consider the feasibility of the timeline associated with these new interaction checks for vendors, providers and hospitals.

Additionally, eHI is concerned about drug formulary checks. Although there are hospital formularies in use and this functionality is available within hospital EHRs, the required use of external formularies for eligible hospitals or critical access hospitals (CAHs) could introduce conflicts with existing hospital error reduction and patient safety efforts.

Engage Patients and Families in Their Care

eHI agrees with continuing the Stage 1 objectives set forth by the Meaningful Use Workgroup:

1. Provide an electronic copy of health information, upon patient request.
2. The use of EHR enabled patient specific educational resources.

In some objectives, eHI urges additional clarification or definitions, including:

1. Online secure messaging – eHI encourages the use of online secure messaging but requests a precise measure of what is included and what is excluded within this term. While there are a range of options available to facilitate communication with patients there should likewise be a range of options allowed for this objective.
2. Patient preference for communication medium recorded – The definition should be specified with sufficient time to ensure that EHRs incorporate the new values. eHI supports the proposed 20% threshold.

Challenging thresholds: eHI recognizes the intent of the Workgroup for Stage 2 to be a stepping stone, but we urge ONC and CMS to consider feasibility when setting thresholds. These include:

1. Provide clinical summaries for each office visit – eHI strongly supports this concept, but again is concerned that the timeframe is expressed in hours, and recommends that it should instead be expressed in business days. eHI also suggests that the current standard of three business days is retained. eHI recommends careful consideration by ONC and CMS of the workflow implications for providers of retaining the current timeframe.
2. Measures to provide timely electronic access (EP) – eHI supports making information accessible to patients, but supports the use of multiple mediums rather than limit the access via one approach. In addition, we urge the definition of the word portal and the clarification of the use of the term “office visit”.

Improve Care Coordination

eHI agrees with the direction of the workgroup recommendations, specifically:

1. Provide summary of care record – eHI supports the usage percentage for Stage 2. In addition, eHI recommends that the Workgroup propose that a material but achievable percentage of the provision of the summary of care record must be transmitted electronically, consistent with standards-based capabilities. This approach will move the HIE objective beyond a test to support care coordination via health information exchange.

In some objectives within this health policy priority, eHI urges additional clarification or definitions, including:

1. Connect to at least three external providers in a primary referral network or establish ongoing bidirectional connection with at least one HIE - eHI supports this objective, yet urges the Workgroup to define the term "primary referral network," and define the term "connect" in the context of the three external providers in the primary referral network.
2. Perform medication reconciliation at care transitions- eHI urges the Workgroup to clarify the definition of "care transitions" that trigger this requirement.
3. List of care team members – eHI urges the Workgroup to define the term "care team members" and consider that a broad definition of this group may result in expensive administration control and may not be actionable by all EPs and EHs. eHI also recommends that at least one person of the defined care team is documented via structured data as the member of the patient care team responsible for 10% of the patients seen by the EP.
4. Longitudinal care plan – eHI urges the Workgroup to define "longitudinal care plan" and the "high priority health condition." The Workgroup is also asked to consider the applicability of this objective to all types of EPs and EHs.

Improve Population and Public Health

eHI agrees with the proposed transitions from Stage 1 menu to Stage 2 core for submission of public health data. Likewise, it is important to identify gaps in necessary preventive care.

Requirements language: eHI supports that the capturing of public health data should continue in the Stage 1 language, particularly the requirement for the submission of data per state law and practice requirements. We are concerned that as data is received from multiple public health agencies, the capturing of information may not occur under any single, specific law.

Specific Questions Posed by the Meaningful Use Workgroup

1. How can electronic progress notes be defined in order to have adequate specificity?

eHI recognizes the importance of data being included in the record and therefore urges the Workgroup to not specify the specific format for electronic progress notes. In addition, there are variations across providers relative to the definition of a progress note. At this time, the issue of standardization of progress notes across providers should be addressed separately, by the HIT Standards Committee, in the support of a transparent process for the development of an appropriate standard. In this interim, eHI recommends linking to other information to make the content in the note searchable.

2.For patient/family access to personal health information, what standards should exist to regarding accessibility for people with disabilities (visual/hearing/speech/mobile impairments)?

eHI agrees that web tools must be compliant with existing federal requirements (Section 508 of the Rehabilitation Act, and Section 251 of the Communication Act, for example). Moreover, requirements must be informed by existing standards. However, specific standards for portable health insurance access should not be considered as a goal for Stage 2, rather a focus of Stage 3.

3. What strategies should exist to address the barriers to patient access, such as limited internet access, low health literacy and/or disability?

eHI suggests that the HITPC consider the specifications for health literacy and cultural competency as a tool to address barriers to patient access, particularly in the objectives and measures included in the patient and family engagement health policy priority area. These two elements are critical in the delivery of high quality care.

4. What is provider and hospital experience in the incorporation of patient-reported data (self-entered PHR, survey data, home monitoring data, etc.) into EHRs?

eHI supports the use of standards to import structured data, recognizing that it is critical to the long-term goal of advancing patient-centered care. HL7 standards can tag data so that it is flagged as patient-reported, while not disrupting the clinical data in the EHR.

In addition, at this time, there is not enough information on the amount of data that is directly moving from device to EHR to accurately state the experience of providers or hospitals in the incorporation of remotely gathered information. eHI recommends that the Workgroup consider that the data from devices is generally not directly transmitted but often goes through a third party that “arranges or organizes” the information for presentation to the recipient.

Finally, eHI recommends that an inquiry into EP and EH experiences should separate and prioritize the understandings by the source of the data (self-generated in a PHR, patient-reported data, home monitoring technology or data directly from a device). Additional work is required to understand how a validation mechanism for patient-entered data would work and the possible impact of patient-generated data on medical liability.

5. For future stages of Meaningful Use, should CMS provide an alternative way to achieve MU based on the demonstration of high performance on clinical quality measures?

eHI supports that only on a targeted basis, with very specific criteria, should alternative ways be available to achieve Meaningful Use based on high performance on clinical quality measures. EHRs are a tool that can drive quality. Moreover, there should be a consideration of process measures, within any alternative made available in future stages of Meaningful Use.

6. Should Stage 2 allow for a group reporting option to demonstrate Meaningful Use at the group level for all EPs in that group?

Although PQRI has two group reporting options, the Workgroup must consider that additional investigation will be required to ensure that individual accountability for the use of EHRs remains visible and that the needed EHR reporting issues can be properly and timely addressed. This is an issue of timing, as the accuracy of the measurement of measures within the EHR is challenging.

7. In Stage 1, as an optional menu objective, the presence of an advance directive should be recorded for over 50% of patients 65 years of age or older. We propose making this objective mandatory and to include the results of the advance directive discussion, if available. We invite comment on this proposal or to offer suggestions for alternative criteria in this area.

eHI supports making advance directive information readily available. There is value in getting advanced directive information into the system, even if the information is limited and not linked to an advance directive that resides elsewhere. There is concern about the legal requirements associated with an advance directive in EHRs – whether or not the provider is required to confirm that the advance directive is still accurate or if they are to assume it is accurate. eHI recommends that the Workgroup address this issue to provide clarity to stakeholders.

9. What additional Meaningful Use criteria could be applied to stimulate robust information exchange?

eHI supports the ability of EPs and EHs to meet the Meaningful Use requirements through the use of health information exchange. Stage 2 requirements remain focused on EHRs and do not allow providers enough room to utilize health information exchange as a means to meet the Meaningful Use requirements. An example is to incorporate the following language that would allow EPs and EHs to use health information exchange to meet the requirement: "or establish an ongoing bidirectional connection to at least one health information exchange with this functionality enabled."

eHI urges the Workgroup to propose that a material but achievable percentage of the requirement for provision of a summary of care record be accomplished via electronic transmission, consistent with standards-based capabilities. Use of health information exchange, as a noun and as a verb, should be encouraged throughout Stage 2 as an option for increasing electronic communication with patients and their families.

10. There are new objectives being considered for stage 3 where there is no Stage 2 "stepping stone" objectives suggested. We invite suggestions on appropriate Stage 2 objectives.

There are ways to evaluate whether these suggestions are MU objectives or issues of functionality of EHRs and eHI urges the workgroup to consider this question before an objective is proposed for Stage 2 or stage 3.

Conclusion

eHealth Initiative appreciates the opportunity to submit comments on the preliminary recommendations for Meaningful Use Stage 2. eHI supports efforts that ensure that Stage 2 achieves its intended goals of acting as a stepping stone to subsequent stages of Meaningful Use and supports health information exchange. Together these actions will result in a connected system of health that delivers optimal care in a cost-effective way and does so in an increasing patient-centered manner.

We look forward to providing further information in support of your efforts. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative