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January 14, 2013

Office of the National Coordinator for Health Information Technology
Attn: Farzad Mostashari, MD, ScM
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 729-D
Washington, D.C. 20201

RE: HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)

Submitted Electronically

Dear Dr. Mostashari,

eHealth Initiative welcomes this opportunity to provide comments on the Request for Comment (RFC) Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs) as issued by the Office of the National Coordinator (ONC) for Health Information Technology (HIT), HIT Policy Committee.

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 IT that is practical, sustainable, and advances high quality patient care. The comments below were developed through our multi-stakeholder consensus process.

eHI appreciates your efforts to advance the EHR Incentive Program through the collection of comments to inform the development of Stage 3 in a manner that facilitates the mobilization of electronic health information to address the health of people, the health of populations, and the need to slow the growth of healthcare costs, while being responsive to the needs of stakeholders. This program is integral to the creation of a healthcare system that is patient-centered, safe, timely, effective, efficient and equitable.

eHI had expressed strong support in comments for the Stage 2 proposed rules for the expansion of health information exchange (HIE) in Stage 2. As Meaningful Use Stage 2 represented a

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transition from data capture to data use in the support of advanced care processes and improved outcomes, it is important to also be mindful that the exchange of information is critical to the success of various health initiatives that have been and are being launched, as all are part of an effort 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 EHR Incentive Program will advance the larger health care goals expressed in numerous Medicare, Medicaid and private sector initiatives.

Since 2004, eHI has fielded a comprehensive survey assessing the current state of data exchange within the United States and the results enable us to understand the current HIE environment as it relates to providers, hospitals, and other stakeholders. Over the years, this survey has grown from one that examined the nascent stages of HIE, into one that provides insight into the overall progress and growth of Health IT and HIE throughout the country.

eHI's 2012 Report on Health Information Exchange found the following:

- Rates of data exchange participation are increasing
  - 322 organizations were solicited to take the survey in 2012, up from 255 in 2011
- Support and usage of Direct messaging is growing.
  - 59 HIE organizations currently offer Direct and 53 plan to support Direct in the future, up from 25 HIEs offering Direct in 2011
- Federal funding is still supporting advanced initiatives.
  - 27 of the advanced HIEs surveyed identified federal funding as their most substantial form of federal funding HIEs are playing a key role in healthcare reform.
- More than half (109) of the initiatives reported that they are currently supporting ACOs and/or Patient-Centered Medical Homes (PCMHs) 63 indicated that they plan on doing so in the future.
- Many initiatives are participating in the State Health Information Exchange Cooperative Agreement Program, which has accelerated HIE capability and progress.
- In 2012, the majority of initiatives responding to the survey (70%) reported active involvement with statewide HIE or State Designated Entities (SDE) efforts.

According to information released by the Centers for Medicare and Medicaid Services (CMS), as of November 2012, over 335,000 eligible professionals (EPs) and just over 4,000 eligible hospitals (EHs) had registered for the Medicare or Medicaid incentive programs. Just over $5.1 billion has been paid for Medicare meaningful use and about $4 billion for Medicaid health IT incentives, of which $3.6 billion was for "adopt, implement, upgrade" (AIU) and approximately $360 million for meaningful use. Medicare Advantage payments were approximately $189 million; with 96,426 Medicare EPs, 65,625 Medicaid EPs, 11,117 Medicare Advantage EPs and 3,393 hospitals having been paid for meaningful use or AIU. Nearly 65% of all eligible hospitals have received an EHR incentive payment for either MU or AIU, and approximately 25% or 1 out of every 4 Medicare EPs are meaningful users of EHRs.[i] Based upon these findings the support

for and implementation of EHRs continues to accelerate. We believe there is much to learn and experience from Stage 1 and ultimately Stage 2 as participants begin reporting.

General Comments

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

- Interoperability as a prerequisite for Stage 3
- Stage 3 Should Focus on Taking Full Advantage of Stage 2 Capabilities
- Align policy with technical capabilities
- Improved quality measurement and reporting initiatives
- Increased Patient Engagement
- Flexibility in Regulation and Timing to Support Participation

Establish interoperability as an essential prerequisite for Stage 3

The increased emphasis on interoperability in the Stage 2 program represents a significant step forward from Stage 1. eHI applauds moving toward the use of standards-based electronic exchange of summaries of care between providers to improve care coordination as well as the objective to improve quality, safety, and efficiency, while reducing health disparities by generating and transmitting permissible prescriptions electronically (eRx). As CMS states in the Stage 2 final regulation, there are more demanding requirements for e-prescribing, incorporating structured laboratory results, and the expectation that providers will electronically transmit patient care summaries with each other and with the patient to support transitions in care. Increasingly robust expectations for health information exchange in Stage 2 and Stage 3 would support the goal that information follows the patient.[ii]

The exchange of information can only be enhanced and supported by the continued development and evolution of EHR interoperability. In its current state, the Health IT infrastructure is relatively immature to support the robust exchange of health information. Interoperability serves as a foundation for successful exchange of information that supports care coordination, patient engagement, public health reporting, and the ability of EHs and EPs to meet the demands of Stage 2. We expect that the Stage 2 capabilities and requirements will build upon substantial private sector progress to date and urge ONC to continue its focus on the additional supporting infrastructure to enable Stage 2 and anticipated Stage 3 exchange and interoperability goals. The development of a Meaningful Use Data Set by ONC that facilitates reporting for all summary of care records, care transitions, discharges, and patient access is step in addressing interoperability challenges however much more must be addressed to accelerate these efforts. Therefore we strongly urge ONC and CMS to establish interoperability as the Stage 3 priority, by focusing on the essential components of interoperable health information systems.

As noted in the RFC, the HITPC has proposed a query-based exchange in Stage 3. eHI supports the stated intention of adding this function, and we encourage ONC and CMS to build the functions and certification requirements on standards and profiles that have been previously developed by standards and profiling organizations such as HL7 and Integrating the Healthcare Enterprise (IHE). These standards and profiles are in wide use by public and private organizations, and we believe the industry will be best served by leveraging those standards already in existence to advance interoperability and exchange of health information among EHRs.

The integration of a standards based approach for query and interoperability is critical for continuing the acceleration of adoption and implementation of EHRs and ultimately is less expensive. At the same time, we recommend ONC and CMS be mindful of the immediate financial burdens associated with implementing standards and work to enable a widely available affordable network, patient matching functionality, and the development of provider directories to allow for continuous bi-directional exchange of information among providers.

Recommendation: To gain a better understanding of the readiness for interoperability and exchange of health information, eHI recommends ONC and CMS evaluate and learn from state HIEs and the Beacon Community grantees, public-private initiatives such as Healtheway and the private sector Care Continuity Consortium to inform next steps towards advancing interoperability and sustainability.

Stage 3 Should Focus on Taking Full Advantage of Stage 2 Capabilities

Stage 2 places a more robust emphasis on the exchange of information supported by a foundation that rests upon terminology and technical standards, including data "package" and transport standards. Within initial implementation of Stage 2, these are still emerging capabilities not only for providers and hospitals, but other stakeholders as well, which will require more than two years for full development and deployment.

ONC maintains its commitment to support standards-based exchange as indicated in the Stage 2 final rule, "If we do not see sufficient progress or that continued impediments exist such that our policy goals for standards-based exchange are not being met, we will revisit these more specific measurement limitations and consider other policies to strengthen the interoperability requirements..." [iii] ***eHI supports this objective and believes the development of Stage 3 should, therefore, focus on a less prescriptive model than was proposed in the RFC, in favor of one that encourages and assists providers in taking advantage of the substantial interoperability capabilities established in Stage 1 and Stage 2***. Healthcare stakeholders need time to address the requirements for Stage 2 in order to inform and share experiences for the development of Stage 3. For example, in Stage 2, the Computerized Provider Order Entry (CPOE) objective required additional orders from laboratory and radiology for inclusion of the measure reporting.

This functionality has changed significantly and requires complex integration and testing efforts to ensure data flows appropriately for patient care. In addition, the Summary of Care objective and associated measures (SGRP 303), as implemented in Stage 2 also require significant modifications from Stage 1 which consolidated other measures and also requires the ability to exchange data with another setting or provider of care.

Recommendation: eHI believes there is much to learn from experience with Stage 1 and Stage 2 processes coupled with the changing healthcare models that require the use of Health IT. As stated in the ONC Standards and Certification final rule, eHI supports and recommends the HITPC, ONC and CMS make every effort to support continued progress in Stage 2 and if necessary, revisit the requirements and ensure steps are taken to further the goal of interoperable EHRs.

Align policy with technical capabilities

The development of Stage 1 and Stage 2 of the EHR Incentive Program has occurred in rapid succession, thus providing limited learning opportunity from measure reporting that supports the Core and Menu objectives, Clinical Quality Measures (CQMs) and the ONC certification standards and certification requirements that serves as a foundation for the program. Moreover, the year 2014 presents an additional compliance requirement for the implementation and use of the updated classification system, ICD-10-CM/PCS, which will significantly impact stakeholders in the healthcare community. This requirement overlaps with the beginning of the allowable reporting period for stage 2 thus incurring significant regulatory changes.

Recommendation: As Stage 3 is developed, allow time for lessons learned and experiences to be shared from Stage 2, and for Health IT to adapt to a variety of regulatory requirements in the next several years.

Improved quality measurement and reporting initiatives

eHI urges ONC and CMS to accelerate the work of identification, testing, and refinement of CQM electronic specifications that can be readily implemented by EHRs, provide valid data at a reasonable cost, 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 alignment, Health IT infrastructure and 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 and vendors during the measure development process.

We encourage the HITPC to emphasize the selection of measures where new opportunities with Health IT functionality are being advanced by meaningful use functional criteria. Previously,

paper records and manual processes offered limited options for quality measurement. Providers, hospitals, measure developers, etc. struggled to take advantage of clinical data to inform the development of quality measures, particularly in areas where quality measures did not previously exist.

We support the need for utilizing a validation and testing process equivalent to National Quality Forum (NQF) endorsement before measures are used in quality reporting or payment programs. While EHRs open an opportunity for exploring new areas for developing quality measurement, CMS and the HITPC must be mindful of the need for harmonization of quality reporting across Medicare programs, including meaningful use. To that end, Congress authorized the Measure Application Partnership (MAP), a public-private partnership convened in 2011 by the NQF to advise the Department of Health and Human Services (HHS) on the selection of quality measures for public reporting and performance-based payment programs in alignment with the National Quality Strategy. The MAP convenes stakeholder groups to balance the interests of consumers, businesses and purchasers, labor, health plans, clinicians and providers, communities and states, and suppliers.

Recommendation: Enable an informed and consistent approach allowing for the development and/or identification, 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 fewer measures for Stage 3, and to be very selective with the measures chosen.

Increased Patient Engagement

eHI applauds ONC's continued consideration on how to increase and encourage patient engagement.

Recommendation: Promote continued learning and evaluation through surveys, testimony, and other forms of responses regarding how patients can and want to become more engaged in their care.

Flexibility in Regulation and Timing to Support Participation

The HITECH legislative provisions do not restrict how the EHR Incentive Program is implemented in terms of timing and length of the stages and content. Therefore, the statute allows for flexibility and refinement over time. With the technical specifications for Stage 2 only recently released in late 2012, four months following the final rule, EPs, EHs, vendors, and other stakeholders were left with little time for planning and preparing for this stage. Even with the publication of Final Rules and the technical specifications more information is still required to inform the development of Stage 2. At a minimum, 18 months in advance is necessary to process and translate the information into understandable material to support people, process,

and technology. Although the emphasis is the exchange of information, this functionality is still an evolving capability not only for providers and hospitals, but vendors as well.

eHI urges that a realistic assessment of the timing of Stage 3 relative to release of the Final Rule and all associated materials be considered and inform the planning for future stages and associated regulations. We strongly recommend all required materials, including the final quality measure specifications and certification test scripts be made available no later than 18 months before the start of Stage 3.

Beyond initial implementation of Stage 3 and consistent with what HITECH permits, we suggest that any subsequent revisions to Meaningful Use and certification focus on maintenance changes needed to keep certification and meaningful use requirements current with standards and leverage emerging technology and practice for maximum use of Health IT. This approach reflects the fact that the Medicare incentives will be completed, and that it will be feasible and appropriate to let normal interactions between providers and vendors resume driving future product development and evolution of EHRs and other health IT platforms.

Calling for a refinement in progress does not reject the course set by the Congress in creating this program, or its implementation by ONC and CMS. This reflects application to public policy of the ability of industry stakeholders to align their programmatic abilities, aimed at encouraging technology adoption, with a focus on iteration and incremental approaches, and flexibility in responding to feedback and changing environmental conditions.

Recommendations:

- Allow for appropriate timing between final rule and technical specification publication and the deadline for meeting the reporting requirements for Stage 3.
- 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.
- Evaluate alternative approaches to reporting CQMs and Core and Menu Set measures.

Additional questions submitted by the HITPC

MU01 - Currently, providers have to meet all MU criteria to receive incentives. Is there flexibility in achieving a close percentage of the objectives, but not quite achieving all of them? What is the downside of providing this additional flexibility? How will it impact providers who are achieving all of the MU criteria? If there is additional flexibility of this type, what are the ways this can be constructed so that it is not harmful to the goals of the program and advantageous to others?

eHI supports the need for reporting flexibility within the program and as the HITPC suggests, exploring mechanisms of the program whereby the requirement of "all or nothing" can be

modified. Perhaps the program should focus on achieving a certain level of success within a broad array of measures and allow higher levels of use for some measures to offset lower performance against others. Alternatively, considering different paths for different types of specialties may allow the opportunity for appropriately recognizing diverse contributions of specialty providers.

As the regulations are developed, we urge ONC and CMS to provide clarity regarding the expected outcomes of the information that is reported. We believe the program should focus less on "how" something is accomplished versus "what" data is to be reported to demonstrate meaningful use of EHRs. Providing refinement in what is reported and the standards and certification requirements needed to support such reporting provides EPs, EHs, vendors, and other stakeholders the tools which they can advance the program.

MU02 - What is the best balance between ease of clinical documentation and the ease of practice management efficiency?

Generally, we do not see conflict between ease of clinical documentation and practice management efficiency. The common goal in both cases should be accurate documentation achieved in ways that take optimal advantage of health IT capabilities without negatively impacting practice management workflow and efficiency. We support the need to clinically document from the perspective of providing quality patient care; however, Health IT must also strengthen a provider's ability to use EHRs that allow the capture, use, storage, and access to structured health information in a consistent manner.

MU03 - To improve the safety of EHRs, should there be a MU requirement for providers to conduct a health IT safety risk assessment? Are there models or standards that we should look to for guidance?

eHI understands the need for ensuring the safety of health IT and taking steps to mitigate areas of risk when in use. However, we believe this will be an ongoing policy consideration for the incentive program, as well as other programs that require the use of Health IT, medical devices, and other mechanisms to capture, store, and utilize patient data for treatment. We encourage the HHS to continue further analysis and exploration of this focus area through testimony, sharing of best practices, and other information sharing initiatives, and its work as a result of ONC's recently published *Health IT Patient Safety Action and Surveillance Plan.*

In addition, in July 2012, as part of the Food and Drug Administration (FDA) Safety and Innovation Act, Congress required FDA, in consultation with ONC and the Federal Communications Commission (FCC), to publish a report "that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." The FDA is required to produce the

report by January 2014. eHI recommends that the HITPC consider the recommendations from these reports in the formulation of future recommendations to the ONC on future stages of the EHR Incentive Program.

Finally, we believe that responsibility for patient safety related to Health IT is a shared responsibility among providers, HIT vendors, patients, and other stakeholders. In considering the merit of a required safety risk assessment, we do not believe mature standards are in place for such an assessment and also believe introducing such a requirement could provide an excessive burden on providers.

MU04 - Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing certain sensitive health information, including restricting the recipient's further disclosure of such information.

- ***How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?***
- ***How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?***
- ***Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today's EHRs and HIEs?***

In 2007, eHI developed the "*eHealth Initiative Blueprint: Building Consensus for Common Action*" which is a shared vision and a set of common principles, strategies and actions for improving health and healthcare through Health IT and health information exchange, developed by a broad, collaborative, and transparent process led by the many diverse stakeholders in healthcare.

One area of focus for us was the management of privacy, security and confidentiality. The Blueprint focused on developing questions for thought and did not intend to answer the questions, but rather serve as a starting point for continued dialogue. We believe there continues to be room for progress in these areas:

- Transparency
- Collection and Use of Personal Health Information
- Individual Control
- Security
- Audit
- Accountability and Oversight

MU05 - The HITECH ACT has given a lot of emphasis to EHRs as the central distribution channel for health information, but there may be limits on how much we can add on to EHR technologies. As additional program demands are added onto EHRs, what can be done to foster innovation to share information and receive intelligence from other, non-EHR applications and services that could be built on top of that data architecture?

We urge HHS to invest in and further develop the infrastructure to accelerate information exchange. The Regional Extension Centers (RECs), Beacon Communities, State Health Information Exchange Cooperatives, and the Strategic Health IT Advanced Research Projects (SHARP) Program are grantees of ONC that have established programs to support the acceleration of implementation and use of EHRs. We encourage the HITPC to recommend the grantees report to ONC their plans for outreach and broadening stakeholder input for lessons learned and other valuable contributions to inform quality measure development. We also believe HHS can leverage the CMS Medicare and Medicaid Innovations Center (CMMI) to experiment and better understand where vulnerabilities lie as they begin considering and looking beyond the EHR Incentive Program as it transitions to the penalty phase of the program.

Further, we believe building a library of standard implementation guides for most common use cases would be beneficial in support of further enhancing intra-provider/organizational interoperability. To date, substantial interoperability has been achieved within the boundaries of an organization, but many implementations were purposefully built for a specific combination of systems for that specific provider/organization and required significant customization, interfaces and middleware installation. We do not believe that the standard referenced above (e.g., C-CDA) are suitable for most of those use cases. Intra-organization interoperability requires substantial workflow management support that C-CDA, Direct or Exchange does not support. Expansion of the Laboratory Results Interface, upcoming Laboratory Orders Interface, and eDOS implementation guides would be examples of guides that can provide a starting point for establishing an intra-provider/organization interoperability library.

MU06 - What can be included in EHR technology to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based. This capability will need to support measures that occur in all stages of MU (e.g. there are yes/no measures in stage 1 that still need to be supported). Are there objectives and measures that should be prioritized to assist providers in showing that the capability was enabled during the reporting period?

This is a complex issue; however, it is generally reasonable to expect an EHR to report evidence of events that occur. It is far more challenging to report on events that happen partially within and partially outside of an EHR and more generally, certain yes/no items can be extremely challenging to track. For example, it can be very complex to track use of clinical decision support (CDS) interventions, given the range of the types of possible CDS interventions.

Tracking submissions to Public Health could also be complicated by varying reporting frequencies and might not be best tracked within an EHR.

Also, audit reports might not be the best means to track certain types of functions and there could be performance issues with certain types of auditing. The HITPC should consult with providers and vendors on specific items for suitability for tracking through automated reports. There is unlikely to be a single solution for all yes/no items as this requires significant complex coding to accomplish this type of data capture. We recommend the use of measures that rely on simple counts and deployment of functionality, rather than complex percentages based on multiple denominators. Additionally, we urge testing of the selected measures to assess whether they are feasible to calculate before they are finalized in meaningful use requirements.

Quality Measures

eHI applauds CMS' effort and acknowledgement to begin aligning quality reporting initiatives as included in Stage 2 and demonstrated in the Physician Quality Reporting System (PQRS) pilot program where EPs have the ability to satisfy meaningful use objectives to report CQMs through both the Meaningful Use program or by participating in the PQRS. We believe further alignment of quality reporting programs will continue to prevent duplication of efforts and serve as one component in preventing increased administrative burden.

eHI agrees with the HITPC's recommendations (established within the RFC) that measures should leverage, to the greatest extent possible, data captured in the EHR during the delivery of care, while minimizing the data collection burden for providers. To maintain data quality and integrity, patient information should be collected once and leveraged for primary and secondary purposes. This can be achieved only when the infrastructure for information exchange and interoperability is further developed and enhanced. In conjunction with this, the ability to accept downloaded specifications for new measures with little tailoring or new coding is also a desirable goal. An HL7 standard format for documenting the content and structure of a quality measure is the Health Quality Measures Format (HQMF), which supports this goal. The infrastructure serves as the underpinning for all other functions within and among EHR use and interoperability.

eHI recommends CMS expand on the collaboration opportunities for measure stewards, vendors and providers early in the electronic CQM specification process so that challenges can be identified by providers expected to report the measures and vendors expected to support accurate reporting well in advance of the commencement of a new stage of the EHR Incentive Program.

The recent launch of the National Library of Medicine's (NLM) Value Set Authority Center (VSAC), in collaboration with ONC provides downloadable access to all official versions of vocabulary value sets contained in the 2014 CQMs. We believe this is an excellent step forward in providing some consistency in the data used for quality measurement initiatives.

1) *The HITPC asks for comment on the proposition that the measures set should address measures for public reporting and quality improvement, and be meaningful at the point of care:* eHI supports this approach to support public health and quality improvement; however, this should be tempered with the belief that to in order to advance in this area, HHS should balance the burden on providers and select those measures that address areas of improvement, and are flexible in achievement.
2) *The HITPC also asks for comment on the proposition that CQMs should not be "hard coded" into the EHR. Doing so may negatively impact local workflow:* We agree that "hard coding" CQMs can create inflexibility and challenges for the provider. Generally we believe that EPs and EHs should have the ability to configure the CQM calculation to use data elements appropriate to local workflow, specialty and patient population mix. At the same time, we are not certain that the notion of "hard coding" has been fully defined and believe that ONC should not be highly prescriptive on how EHRs support quality measurement. The focus instead should be on the outcomes that are accomplished through the quality measurement system.

A. Patient Centeredness: Broaden Stakeholder Input

Providers may also discuss with patients directly what tools and resources would benefit them to encourage increased engagement in their care. We understand that not all providers have the opportunity for direct patient contact; one way to achieve this may be leveraging patient portals as a mechanism to capture relevant information, such as satisfaction surveys.

B. Patient Centeredness: Patient-reported and Patient-Directed Data

We agree that patient captured data is essential to providing quality patient care; however we believe this is a focus of the EHR Incentive Program that has not been specified further, and raises questions regarding the integration of this information into an EHR. We believe further analysis and exploration is needed to inform next steps on the patient reported data.

D. CQM Pipeline: Measure Development Lifecycle

eHI calls on CMS to evaluate ways to advance from functions that require abstracting a patient's paper record for the purposes of responding to quality measurement requirements, to measures supported by functionality. We call on CMS to conduct this evaluation in coordination with the ongoing activities at CMS to select quality measures for quality reporting and payment in federal health care programs. As discussed earlier in this document EHRs present new opportunities for data collection and reporting that paper and manual processes did not allow for. We believe moving toward electronic data capture and use allows for the development of measures to addresses areas of need that could not be viable within a paper environment.

We believe the clinical quality measure requirements in the EHR Incentive Program should draw from the statutorily created work of the MAP. The Affordable Care Act (ACA) authorizes HHS to engage the multi-stakeholder the National Quality Forum in the MAP to review and make recommendations on quality measures for inclusion in federal health care programs. The MAP will consider more than 500 quality measures and will share recommendations in a report to

HHS in March. That review includes a consideration of the data elements necessary for each quality measure. With the recommendations, we call on ONC to work with those entities responsible for ensuring that EHRs can support the electronic capture of the data elements, perform the measure calculations and successfully report the results.

E. CQM Pipeline: MU Alignment with Functional Objectives

eHI and its members applaud the HITPC's acknowledgement of increased provider administrative burden risks with all quality measurement programs. We support the intent of the HITPC Meaningful Use Workgroup to address this burden by offering recommendations that support HHS' effort to align CQMs across programs. We believe this is a positive step toward more efficient and effective use of EHRs and the leverages the intended use.

Again, as ONC and CMS approach Stage 3 of the EHR Incentive Program we strongly urge moving forward with developing and embedding consistent concepts, processes and mechanisms for data collection, storage and utilization of health information for patient care and quality measurement initiatives.

F. CQM Pipeline: Domains and Exemplars

eHI maintains that HHS should continue efforts to align quality reporting programs in order to prevent increased administrative burden. We believe there is much to learn from Stages 1 and 2 to better understand why certain measures have or have not been selected for reporting. We are hesitant to encourage the HITPC to recommend additional measures for the EHR incentive program without truly understanding the degree to which measures are in use and how they have been able to improve care and outcomes. CMS should evaluate areas of need to help inform the potential for adding or removing certain measures from the program that have either topped out or no longer effective. Given all of these considerations, we urge CMS to consider finalizing fewer measures for Stage 3, and to be very selective with the measures chosen.

G. CQM Pipeline: MU and Innovation

Some provider organizations and state/community-based reporting programs have developed, tested and are consistently using unique eCQMs that are Health IT-enabled and enhance quality care for diverse patient populations across the nation. These practice-level eCQMs typically have not been vetted by national quality endorsement organizations. We believe that where locally developed quality measures exist, they should be leveraging standard tools, mechanisms, and processes that have emerged to allow for the expression of the CQMs in a consistent manner.

Overall, we support and applaud programs that provide some limited allowance for locally developed CQMs, as long as the standards and practices are designed to promote data quality, integrity, ease of interpretation, and are cost effective for implementation. These factors would allow participants to use local measures, and take advantage of other infrastructure that is in place, providing one source of innovation.

H. Quality Improvement Support: Architecture and Standards

1. *Ability to accept downloaded specifications for new measures with little tailoring or new coding*: We support this concept to download the measure specifications as long as the measures are in fact suitable for such downloading. To date, this ability has not occurred for most measures.

2. *Minimal manual data collection or manipulation*: We believe this is a shared goal for all participants in the Meaningful Use program as it helps to reduce the administrative burden, and aspires to maintain data integrity of the information that is collected during patient care.

3. *Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc.), Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions), Ability to build multi-source data records, including claims, patient reported data,* and *Ability to implement machine-readable HQMF that minimizes manual vendor coding*: eHI supports the above concepts as aspirational goals for the EHR Incentive Program; however, given its maturity, level of certification requirement, and current Health IT abilities, it is difficult to provide an informed response. Successful implementation of these features will require continued development and testing not only for the eCQMs but the overall Health IT technology as well. We believe it will be essential remain aware of the continued improvements in these areas as the program matures and experiences from Stage 1 and Stage 2 are distributed. Over time, as the market matures, we believe demand for the functions described will accelerate.

4. *Ability to drill-down on reported measures for QI analyses*: We encourage ONC and the HITPC to provide further clarification regarding the concept of "drill down". It is challenging to evaluate this statement without having a better understanding of what the intended results are. In general, we do not believe that ONC should be highly directive on EHR functionality in CQM reporting but rather let market demand drive the introduction of new and innovative functionalities.

eHI encourages CMS and ONC to provide the appropriate reference guides and other supporting materials that would enable a more positive experience from a development, testing, and user level perspective. The program should allow flexibility for all stakeholders to drive the development of requirements that will meet the needs of achieving meaningful use of EHRs. Should the features and functions become too prescriptive they may hamper the ability of providers and hospitals to leverage the best features, functions, and workflows that support them and the patients they serve.

I. Quality Improvement Support: CQM Population Management Platform

eHI encourages ONC and CMS not to be too prescriptive regarding the development of such new product areas and functionalities. We believe the market will develop the required products and services based on varying provider needs given, the growth of shared savings programs such as Accountable Care Organizations (ACOs) and other new delivery and payment models. This approach will help to establish the framework and guidance from which the development of

products and services can begin. The major ONC role should be development of CQM specification and associated standards that will be used for quality measurement via EHR technology.

Conclusion

eHI is pleased with the progress of implementation and use of EHRs through support provided by HHS. Through ONC and CMS' continued engagement and outreach with Health IT stakeholders to inform, develop and mature the EHR Incentive 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 Request for Comment Regarding the Stage 3 Definition of Meaningful Use of EHRs.

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

[i] Centers for Medicare and Medicaid Services, Update on Medicare & Medicaid EHR Incentive Programs, HIT Policy Committee Meeting, 01/08/13

[ii] "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition (Final Rules)." Federal Register 77:171 (September 4, 2012) p. 53973. Available from http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf Accessed: 1/7/13.

[iii] Ibid (77FR54020).