eHEALTH INITIATIVE
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May 4, 2012

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013
Attention: CMS-0044-P

RIN: 0938-AQ84

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

Dear Administrator Tavenner,

eHealth Initiative welcomes this opportunity to provide comments on the proposed rule for the Medicare and Medicaid Programs Electronic Health Record Incentive Program – Stage 2.

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. The comments below were developed through our multi-stakeholder consensus process. We have attached a list of our members for your information.

eHI appreciates your efforts to advance the Electronic Health Record (EHR) Incentive program 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, particularly patients and continues to build public trust. This program is integral to the creation of a healthcare system that is patient-centered, safe, timely, effective, efficient and equitable.

A critical component in the transformation of our current system into a high-performing, learning healthcare system is an appreciation of the attributes that define such a system and how health IT can enable them. eHI is encouraged by CMS' continued focus on adoption and use of technology to support the realization

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of those attributes generally, and implementation of this activity in a manner that supports patients and their families and providers in the management of health and wellness. The focus on achieving better coordination of care and better outcomes via an inclusive care team with many participants utilizing technology to achieve their goals is critical to realizing this vision. Increased adoption and meaningful use of EHRs in a manner that is expeditious yet balanced by experience will support the development of the healthcare system we seek

In order to achieve the healthcare system described, eHI strongly supports the emphasis on the expansion of health information exchange in this proposed rule. As Meaningful Use Stage 2 represents a transition from data capture to data use in the support advanced care processes and improved outcomes, it is important to also be mindful that the exchange of information is critical to the success of the 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 multiple participants in the health care system. As such, our comments in this letter, while referencing specific suggestions articulated in the proposed rule, are rooted in the belief that programmatic success for the EHR incentive program will advance the larger health care goals articulated in several Medicare, Medicaid and private sector initiatives, particularly those that improve the management and treatment of chronic disease such as heart disease, diabetes and cancer.

Our comments are premised on the following priorities:

1. Emphasis on Interoperability and Health Information Exchange

The increased emphasis on interoperability in the Stage 2 proposal represents a significant step forward from Stage 1. eHI applauds the move from a single test of data exchange in Stage 1 to a requirement for actual standards-based electronic exchange of summaries of care between providers. We are concerned, however, that the proposed rule may be unnecessarily narrow in identifying opportunities to advance exchange among providers, as well as between patients and providers.

For example, we recommend that CMS be explicit on how providers can use NwHIN-type exchange standards and models, such as through health information exchanges and standards-based query-models of exchange, to satisfy the objective and measure associated with the exchange of summaries of care. Health Information Exchange, both when used as a noun and the verb, can support more robust models of clinical data exchange as well as patient access to data, than is articulated in the NPRM. We also support such a broader approach because it will support the future stages in which patient-entered data needs to become accessible by multiple members of the patient's care team. We also support a broader approach because it enables future stages of meaningful use in which patient-

entered data needs to become accessible by multiple members of the patient's care team.

In addition, we applaud CMS for including the requirement that providers address the encryption/security of data that is stored in certified EHR Technology (data at rest). The demonstrated, successful attainment of appropriate administrative, physical, and technical safeguards to secure electronic protected health information (PHI) is central to building trust among all stakeholders in the use of EHRs and the exchange of data.

2. Concurrent Efforts that Support Meaningful Use and National Health Goals

eHI urges CMS to accelerate the work of identification, testing, and refinement of e-specified clinical quality measures (CQMs) that can be readily implemented by EHRs and vendors and that will support both the current and future requirements of meaningful use. eHI also recommends that CMS continue collaboration with ONC on the development and testing of standards that support the capture and collection of data needed by eligible professionals and eligible hospitals to successfully report quality measures, including future measures that will be dependent on patient-entered data. Success in this regard will support successful attainment of the goals of the National Quality Strategy, Healthy People 2020, and other national health initiatives.

eHI supports the focus on clinical decision support (CDS) that is available at the point of care to improve performance on high priority health conditions. Likewise, we are supportive of the focus on computerized physician order entry (CPOE) to document orders in a digital, structured, and computable format that is then used to drive improvements in safety and efficiency. Both of these proposals would benefit from refinement and we urge that CMS carefully consider stakeholder comments on these objectives and measures. We believe this emphasis in the EHR Incentive program on CDS and CPOE will accelerate the success of initiatives such as the Million Hearts Campaign, aimed at focusing attention on the prevention of heart attacks and improving the prescription of and adherence to appropriate medications. We have concerns with the CMS proposal to require that CDS interventions are linked to clinical quality measures (CQMs) given the need for provider flexibility in use of both CDS and CQMs, as well as continued gaps in CQMs available to providers across the spectrum, and also our concerns with particularly e-measures, as noted in our remarks above. Additionally, as will be referenced at a high level elsewhere in this letter, we recommend that CMS reflect on the experience of eligible professionals and eligible hospitals in their use of CDS and CPOE in Stage 1 and share this information with providers and vendors so that challenges may be identified and successfully surmounted in Stage 2.

3. Increased Patient Engagement

eHI is encouraged by the increased emphasis placed upon patient engagement in Stage 2. Objectives that will advance patient access to clinical summaries after office visits, hospital discharge instructions, and patient-specific educational resources help to remove barriers to patient participation in their healthcare. Improved communication will support informed patients who can then play an active role in their care team, all members of which are working to achieve the best health outcomes possible. An increase in patient-generated information and bi-directional data exchange also will support a safer, more open, and efficient healthcare system. We urge CMS to collaborate with ONC in the development and implementation of communication strategies that educate providers and the public about the final Stage 2 requirements and eventual Stage 3 requirements involving direct patient engagement. The plan executed to communicate to the public about the Medicare Part D program is one example of a comprehensive approach to achieving public awareness of significant change in a government healthcare program with millions of beneficiaries.

4. Timing of Meaningful Use Stage 2

eHI appreciates and strongly supports the proposal to delay by one year the initial start of the Stage 2 of the EHR Incentive program, and the need for providers to implement a new edition of certified EHR technology, to 2014. The intent of the delay - allowance for adequate time for preparation and system testing by vendors and providers to meet Stage 2 requirements - is laudable. Stage 2 requirements represent a robust advancement from the data capture and attestation requirements of Stage 1, so if the enhanced requirements in Stage 2 are to be successfully achieved, this additional time for preparation proposed by CMS will need to be fully leveraged by all parties.

In addition, because of the challenges to vendors and providers that will arise, even with the delayed deadline, due to large numbers of providers needing to implement 2014 certified EHR technology in a very compressed time frame, we recommend that CMS provide some revisions in the final rule that address the challenges for providers, vendors, and patients resulting from the fact that all eligible professionals and eligible hospitals who are pursuing meaningful use in 2014 will need to upgrade to 2014 Edition EHRs in a very compressed timeframe.. Such steps will help enable a smooth transition for vendors and providers, to enable more Stage 1 eligible professionals and eligible hospitals to meet requirements for incentive payments, and to encourage those eligible but not engaged to register and participate in the EHR incentive program.

5. Consideration of Meaningful Use Stage 1 Experience

eHI encourages CMS to continue to reflect on the experience in the EHR Incentive program to date as it finalizes advancements for the next stage of the program. Increasing the total number of eligible professionals and eligible hospitals that participate in the EHR Incentive Program is vital to the overall program success. Continuous communication about experiences to date should support ongoing collaboration among public and private sector stakeholders to address issues that could impede provider participation. We urge CMS to continue this approach in the future and augment such efforts with formal evaluations for eligible professionals and eligible hospitals to capture information that may accelerate the identification of barriers to successful attainment of meaningful use. We also recommend that CMS collaborate with diverse stakeholders to survey providers who are not registered to participate in the EHR Incentive program or have not attested to meaningful use, to provide a feedback loop that informs national and local strategies to boost adoption rates and encourage effective use.

6. Regulatory Flexibility to Support EHR Incentive Program Participation

In eHI's Blueprint: Building Consensus for Common Action, which articulates principles, strategies and actions for improving health and healthcare through health IT adoption and health information exchange, we noted that the alignment of incentives is important to accelerating other activities that will yield a significant return. To that end, eHI is concerned that the proposed rule could penalize some providers in 2015 based upon a view of their ability to meet meaningful use requirements in 2013 and 2014 that is too retrospective in its perspective. A scenario in which providers attain meaningful use in a current year but not in a previous year, and thereby simultaneously receive a penalty and an incentive payment, could, in fact, undermine the goal of retaining and bringing more providers into the EHR Incentive program. We request that CMS examine its proposals in this area for unintended consequences associated with the timing of the proposals.

We also support the inclusion of a fourth category of exception for Medicare payment adjustments that are otherwise scheduled to take effect in 2015. The combination of clinical features limiting a provider's interaction with patients and lack of control over the availability of certified EHR technology at their practice locations presents challenges to several specialties, including pathologists, radiologists, and anesthesiologists. Additionally, eHI recommends that CMS revisit the categories of exemptions available to providers to ensure that the providers are not penalized for circumstances that are beyond their control. As an example, additional exemptions may be necessary in instances where a vendor suspends their operations or decides to not seek certification of new generations of products.

Comments on Proposed Objectives and Measures for Stage 2

Provisions Supporting the Advancement of Information Exchange:

Imaging Results (FR Vol. 77, No. 45, p. 13727, 13819):

eHI strongly supports the addition of an imaging objective and measure for Stage 2. Images are a critical element of the information that providers use to diagnose and manage disease and the access to needed images should enhance care and prevent some duplicative imaging tests. We also agree with CMS's proposal to not require images to be stored within the EHR, but rather to be accessible through the EHR, such as by a link to an external system or image repository. We urge CMS to carefully consider comments received on how best to implement this important new objective and measure.

Suggestions on what would push electronic health information exchange beyond what is proposed (FR Vol. 77, No. 45, p.13724):

eHI supports this overall proposal, including moving from a test to actual electronic exchange, but is concerned that the measure requiring electronic exchange of a summary of care record between providers without organizational affiliation who use different EHR vendors may be too limiting. Standards-based exchange should be encouraged among providers who are engaged in the care of common patients without regard to their respective selection of EHR or vendor, and CMS should adjust its proposed numerator and denominator for electronic exchange to focus on the percent of transmissions of care and referrals that occur outside of the provider's organization that involve an electronic summary transmission. A focus on the standards-based exchange that supports and strengthens the relationship among the care team members will support the goal of care coordination.

In addition, as suggested above, we recommend that CMS offer additional clarification concerning the proposal to allow providers to use NwHIN-type exchange standards and models, through health information exchanges and standards-based query-models of exchange, as part of the objective and measure associated with exchange of a summary of care record. Participants in the EHR Incentive Program should be encouraged to use the most robust exchange possible.

Provisions Supporting Care Coordination:

Cancer Registries (FR Vol. 77, No. 45, p. 13728):

eHI supports the menu objective available to eligible professionals asking them to identify and report cancer cases to a state cancer registry, as well as the use certified EHR Technology to support the ongoing submission of such information for the entire EHR reporting period. We recommend that CMS continue to work with the states on state registry requirements, however, and specifically the standardization of what information is collected and how it is collected. In addition, health information exchanges may be an enabler of this menu objective by providing a useful transport mechanism, and we recommend that CMS and ONC collaborate on the development of guidance to state designated entities that can position them as a potential partner of eligible professionals seeking to avail themselves of this reporting option.

We do have some concerns about whether many eligible professionals will be able to utilize this menu item, as we understand that most such submissions now come from hospitals and through very specialized data standards. We think that attestation is appropriate as a measurement for this objective, and we agree that letters from cancer registries would be a reasonable means of supporting this attestation.

Specialized Registries (FR Vol. 77, No. 45, p. 13728):

eHI supports the inclusion of a menu objective available to eligible professionals to identify and report specific cases to a specialized registry, as well as the use of certified EHR Technology to support the ongoing submission of information for the entire EHR reporting period. This menu option may support the collection of specific case information that is currently transmitted by eligible professionals to registries in support of quality improvement initiatives. We recommend that CMS offer additional guidance on the definition of a specialized registry, however, including characteristics of a registry that supports quality improvement. In addition, guidance on the standard for transferring data from EHRs to a registry is recommended. This clarification will provide insight on the similar electronic reporting requirements for the EHR Incentive program and other CMS quality reporting programs where eligible professionals report via registries.

Conclusion

eHealth Initiative appreciates the opportunity provide comments on the proposed rule for the Medicare and Medicaid Programs Electronic Health Record Incentive Program – Stage 2.

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