HIMSS Electronic Health Record Association

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June 30, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program [CMS-1607-P]

Dear Ms. Tavenner:

On behalf of the members of the EHR Association, we are pleased to submit our comments to the Center for Medicare and Medicaid Services (CMS) on the proposed rule, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program.

Established in 2004, the EHR Association is comprised of nearly 40 companies that employ industry experts in the field of health information technology (HIT) with a broad scope of expertise, such as physicians, nurses, pharmacists, technologists, and policy experts. These individuals not only represent the EHR software industry, but also interact with and reflect the breadth of the entire healthcare community. We support the majority of hospitals and practice-based physicians in organizations of varied sizes and specialties that are using digital records to deliver care to their patients. This response was developed through an open, collaborative process engaging representatives from our member companies.

We offer the following comments and recommendations in response to the CMS' continued efforts to align quality measure programs, beginning with the Hospital Inpatient Quality Reporting (IQR) and the Medicare EHR Incentive Programs. As we have commented previously, the EHR Association applauds the plans to align quality measurement across CMS programs and we agree that successful alignment will greatly reduce the burden on both hospitals and the software developer community.

Considerations on Validation Pilot for eCQMs and Manually-Abstracted Measures
We support CMS' stated intention to conduct a large scale pilot test of validation activities beginning in FY 2015, as well as CMS' intention to reimburse hospitals for their participation. However, we also ask CMS to consider several important factors in this validation process.

First, the level of complexity in migration of clinical measures from chart abstraction to the electronic clinical quality measures (eCQMs) cannot be underestimated. The EHR Association has provided detailed comments to CMS and the Office of the National Coordinator for Health IT (ONC) regarding this complexity in many previous comments, meetings, and at the CMS and ONC quality measure Kaizen activities. Although there is general agreement that the science behind development of a quality measure remains consistent between manually-abstracted and eCQMs, there are significant differences between the specifications, collection processes and clinician workflows, all of which can produce non-comparable results. Many of our member companies, as well as other organizations such as the American Hospital Association, have worked with providers to identify the primary reasons for these differences. We strongly recommend that the pilot validation process consider the following significant observations when finalizing the validation pilot plan and subsequent analysis of the results:

- Manually-abstracted measures rely on human readable narrative definitions used by clinically educated professionals, while eCQMs are defined by electronic specifications implemented by engineering staff and utilizing computer machine interpretation, with no human analysis. Because of this latter characteristic, there is no room for error in the electronic specification of the measures. CMS and ONC have acknowledged that virtually 100% of the first release of the 2014 eCQM specifications contained errors, and even with the release of two updated specification versions, stakeholders continue to identify errors.
- The process of manual chart review allows data collection from any documentation source within a medical chart, while EHR certification requirements demand specific data element location and coding for each Quality Data Model (QDM) category. Due to the restrictive nature of the QDM, eCQM data collection and reporting are limited to those instances that fit within the defined definitions.
- Workflow requirements with manual abstraction are less rigid and the clinical coding staff can adjust for any inconsistent provider documentation standards. On the other hand, using the measure specifications provided by CMS, the eCQMs must be strictly calculated by the HIT technology with no opportunity for human intervention, requiring consistent provider documentation using standard terminology to assure accurate data element capture for analysis and results.

We are also concerned that the proposed plan does not reflect the significant role of EHR vendors in this effort. In order to successfully support our customers who may choose to participate, it will be critical for vendors to provide resources to assist in technical requirements as well as the analysis necessary to clearly understand the results of this pilot test. We strongly recommend that CMS consider the EHR vendor role in the final validation test plan, and work with vendors prior to initiation of the pilot to understand some of the variances pointed out previously, as well as the following recommendations:

- Include vendors as a source of information that can help address many of the questions posed in the interview document, thus reducing costs and improving the quality of the final interview process.
- Identify EHR system functional requirements in advance of the pilot and query vendors as to current product capabilities relative to these requirements. To ensure success, the pilot should only include functional requirements that were required in Stage 2 2014 edition certification.
- Acknowledge that there is variation between EHR products, as well as the implementation of an individual EHR across multiple provider organizations. In addition, there is not a one to one relationship in the data entry and capture of a specific data element. For example, depending on the provider workflow, multiple input locations for data entry may be appropriate for the same information in EHRs. In addition, providers customize their systems to meet the specific needs of their organization, which leads to further variability.
- Acknowledge that data can be unstructured in an EHR and that provider documentation can vary and still support the intent of the measure.
- Provide additional guidance as to the purpose of the questions and how it will inform the outcome of the pilot.
- Ensure that the methodology of the validation program does not place undue burden on the providers' or the health system

In addition, we recommend a continued focus on improving the development and testing process of the measure specifications prior to general release to assure their accuracy. We applaud CMS and ONC regarding their recent efforts to improve the development of the specifications. We enthusiastically support the suggestion made during the June 16, 2014 CMS/EHRA meeting to pilot new measures for a year prior to requiring their use in a federal program.

Finally, we strongly recommend postponing any required public reporting of eCQM data, as well as requiring reporting of eCQMs for the IQR program as proposed for CY 2016 until the results of the validation pilot can be fully understood, and any needed improvements implemented.

Annual Updates on CQM Specifications
CMS implemented an annual update process to the eCQM specifications last year. As stated in this current proposed rule, the annual updates are a subregulatory process to incorporate "nonsubstantive" updates into the measure specifications so that these measures remain up-to-date. However, the experience to-date of our member companies has been that the annual updates include very substantive changes, with a high and material impact to both vendors and providers. In the June 16, 2014 meeting with CMS, EHRA and other stakeholders, CMS agreed that further definition of nonsubstantive changes would help guide the measure developers, as well as additional education and information sharing similar to what we provided in the meeting. The EHR Association is looking forward to working with CMS on the implementation of these recommendations as well as the additional ones proposed in that meeting.

There is also general confusion, as well as outstanding policy questions, regarding the need for vendors to undergo certification of the updated measures when earlier versions had already been certified, as well as whether providers must start their measure reporting year with the annual measure updates implemented in their EHR. The responses we have received from CMS and ONC have not clarified these issues, and have been inconsistent. In addition, the Cypress eCQM testing tool is not yet available for certification of the new measures, and to date, we have not received information on when it will be available.

Celebrating Ten Years of Advocacy, Education & Outreach
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June 30, 2014

Given the time between now (June 2014) and October 1, 2014, the start of the measure reporting year for the EHR Incentive Program, vendors and Certification Test Labs do not have enough time to undergo certification and subsequently deliver software to our customers. These customers in turn must implement the updated software, remap clinical data based on the measure changes, test their systems, revise workflow, and provide education to all users on the changes. The impact of this timing constraint means that providers will continue to <u>attest</u> to their eCQMS in FY 2015, rather than submit their eCQMs <u>electronically</u> as CMS would like them to do.

If the annual measure updates continue to contain the same magnitude of revisions in subsequent years, these challenges will continue and likely accelerate in importance. We reiterate our prior recommendation that the annual updates be limited to changes that do not have a significant impact on clinician workflow or require extensive software code changes or recertification of the EHR software. If a measure specification requires more extensive modifications, alternative avenues for scheduling such changes should be considered that would provide ample time to accommodate these activities.

Ensure Continued Improvements to the Electronic Clinical Quality Measure Process
The EHR Association agrees with the CMS goal stated in this proposed rule to simplify and streamline reporting for the various EHR quality reporting programs, so that hospitals will be able to move towards EHR-based reporting for many of the measures that are currently chart-abstracted. Our members have been active participants in the efforts by both the CMS and the ONC to improve the eCQM development and implementation process in order to achieve the benefits of EHR-based reporting. These improvements require focused attention and time, and are critical to ensuring the reliability, accuracy and validity of the eCQMs as CMS and ONC work to align the quality programs.

In the ONC Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria proposed rule, ONC solicited industry support for unified, modularized clinical decision support (CDS) and eCQMs for the 2017 Edition of certified software recently launched through the Clinical Quality Framework (CQF) initiative of the S&I Framework. We agree that the strategy to modularize components of the standards can improve the ability to implement new versions of each standard. At the same time, we are very concerned that the compressed timeline for this initiative does not allow adequate time to ensure that the critical improvements already underway in the eCQM development, testing and implementation process continue to advance, and are not compromised by rapidly changing standards and requirements that are only just evolving. Without thorough development and testing, the ability to accurately measure healthcare quality and outcomes may be compromised. Rather than enhance patient safety, implementation of clinical decision support and clinical quality measures intended to improve care may actually threaten it.

As we have commented to ONC, the inclusion of this new framework for Stage 3 eCQMs is not feasible given the compressed timeline, the current status of the proposed standards, and the scope of the work required. We therefore urge CMS and ONC not to include the proposed unified CDS/CQM standards for 2017 certified electronic health record technology (CEHRT) and Stage 3 CQMs. We also recommend that ONC and CMS consider a more incremental approach to the eventual implementation and adoption of these standards, ensuring that each one has been fully tested and piloted prior to requiring adoption by all EHRs.

eCQM Reporting and Submission Timeline and Method
CMS proposes to align the reporting and submission periods for the EHR Incentive Program and IQR to a calendar year basis for 2015 for providers submitting eCQM data electronically, starting on January 1, 2015. CMS also proposes to only require reporting for the first three calendar quarters, in order to

accommodate the EHR incentive program timelines. In addition, reporting will be also be on a quarterly basis for electronic submission for the EHR Incentive program, in order to align with the IQR program.

In general, the EHR Association agrees with this proposal, and we offer the following recommendations regarding CQM reporting for the EHR Incentive Program. First, in recognition that some hospitals may not be ready to submit electronically the first quarter of 2015, we recommend that hospitals who elect to submit their CQMs through attestation for the full fiscal year could also begin submitting their data electronically for any of the calendar quarters as a "pilot" test, in order be fully prepared to begin electronic submission the following year.

CMS has also indicated that the use of the QRDA III aggregate data format for electronic submission of eCQMs is again not feasible for 2015. We recommend that CMS therefore remove the EHR Incentive program requirement for QRDA III for eligible hospitals, and that ONC also remove it from the certification requirements. It is not productive to continue requiring each vendor to certify to this standard if it will not be utilized.
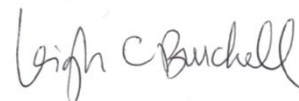
Conclusion
On behalf of the EHR Association and our member companies, we appreciate the opportunity to share our comments on the continued alignment of the Hospital IQR program with other Medicare and Medicaid programs, beginning with the CQM component of the EHR Incentive Program outlined in the proposed rule. We look forward to our continued work with CMS in our shared goals of maximizing the use of EHRs in the collection and reporting of clinical quality measures, while reducing the burden on providers.
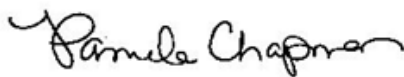
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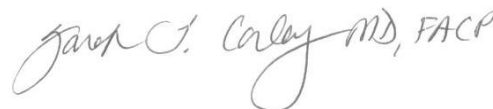Michele McGlynn
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e-MDs

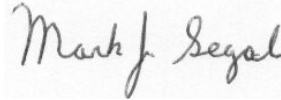Sarah Corley, MD
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About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.