HIMSS Electronic Health Record Association

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

[Filed Electronically]

RE: Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting [CMS–3278–NC]

Dear Ms. Tavenner:

On behalf of the members of the EHR Association, we are pleased to submit our comments on the Center for Medicare and Medicaid Services' (CMS) Request for Information (RFI) on from hospitals, electronic health record (EHR) vendors, and other interested parties regarding hospital readiness beginning calendar year 2014 discharges to electronically report certain patient-level data under the Hospital Inpatient Quality Reporting (IQR) Program using the Quality Reporting Document Architecture (QRDA) Category I.
Our response was developed through an open, collaborative process engaging representatives from our 40 member companies that represent the majority of installed, operational EHRs in the US. On behalf of these members and our collective customers – hospitals and physicians of varying sizes and specialties, we provide detailed input below to the questions posed in the CMS RFI that were relevant to EHR vendors in general.

How do hospitals and vendors perceive the alignment of EHR-based reporting and hospital quality reporting programs? What are the foreseen benefits and challenges?

The EHR Association applauds the plans to align measure reporting across CMS programs. This alignment will greatly reduce the burden on both providers, who today are challenged with complying with multiple quality measurement

programs, and the vendor community, as we strive to provide solutions for our customers.

However, there are also many challenges for deployments in calendar year (CY) 2014, Clinical quality measures (CQMs) are not yet optimized for electronic capture, calculation, and reporting. The electronic CQM (eCQM) specifications were based on retooled, manual quality measures, and many errors have been identified within the specifications. In addition, it cannot be assumed that the original, chart-abstracted measures align with the retooled eCQMs and produce comparable, consistent results. We also note that the QRDA standards for Category I and Category III are relatively recent HL7 standards, and there has been no broad-based testing of these standards.

An additional barrier to the potential alignment of EHR-based CQM reporting with the IQR program in the calendar year 2014 originates from the required reporting periods for 2014. All providers, regardless of their stage of meaningful use, are only required to demonstrate meaningful use for a three-month EHR reporting period in fiscal year (FY) or CY 2014. This approach was taken so that all providers who must upgrade to 2014 certified EHR technology (CEHRT) will have adequate time to implement their newly certified EHR systems. Many hospitals will not have implemented the 2014 eCQM software at the beginning of CY 2014, and may not use the software in full production until August 1, 2014, and therefore, will not have a full year of measurement data or experience with the eCQMs and the QRDA standard.

As we have stated in past comments, CMS and ONC should continue to invest in quality measure alignment, infrastructure, and standards. Building on the foundation begun in Stage 2, this process should incorporate the time needed for establishing the necessary standards, field testing, and collaboration among measure developers. We cannot short-cut the rigor of this development process, which is critical to the measurement of quality and outcomes in healthcare as we move toward the alignment of EHR-based reporting and hospital quality reporting programs. Without this preparation, the implementation of eCQMs intended to improve care may actually threaten, rather than enhance, patient safety. These unintended consequences could become a potential barrier to the adoption of EHR technology and innovative new models of payment and care delivery.

Do hospitals and vendors envision being able to meet the criteria for reporting clinical quality measures electronically for the EHR Incentive Program as set forth in the EHR Incentive Program – Stage 2 final rule (77 FR. 53968) and any related guidance issued? If not, what are the issues in meeting the requirements and what additional information is needed?

We certainly expect that the EHR developer community will be ready in time for our customers to attest for meaningful use given the CMS timelines, although we cannot speak for specific companies. In particular, the EHR developer community is working hard to implement the Stage 2 requirements for reporting eCQMs, along with all of the other final rule requirements for the EHR incentive program, in order to ensure our customers can implement 2014 certified software within their desired timeframes. It is important, however, to emphasize that we face multiple challenges with the current timeline of available final rules, quality measure specifications, and certification test scripts and tools.

For Stage 2, all initial materials were not final until late December 2012 — almost four months after the final rules were published, and *less than one year* before Stage 2 starts for hospitals. We are still identifying issues in the quality measure specifications and value sets, and are expecting additional updates to these measure specifications and value sets. In addition, although the EHR Association understands and agrees with ONC's efforts to ensure that EHR solutions are tested for accuracy in the calculation of CQMs, and we support this goal, we are concerned over the current status of the Cypress testing tool, test procedures, and test data. We feel very strongly that these issues could threaten the

successful and timely CQM certification of our EHR products. We refer you to the letter and associated documentation of issues and recommendations sent by the Association to ONC on January 22nd, 2013.
Is the hospital already participating in or planning to participate in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and Critical Access Hospitals (CAHs) ("Pilot")? The pilot provides eligible hospitals and CAHs with an opportunity to meet the CQM reporting requirements of the Medicare EHR Incentive Program through electronic submission of CQM data. The pilot is a voluntary electronic reporting method used to satisfy the CQM reporting requirements for the Medicare EHR Incentive Program. If not, what barriers prevent the hospital from participating?

Although we understand that this question is targeted to our customers, we would like to respond from an EHR developer perspective, primarily because our customers are dependent upon their vendors in order to participate in this pilot. We understand that for the 2012 "pilot", there was minimal participation from hospitals and their associated vendors. In our experience, most of our customers, many of whom were in their first year of meaningful use, were focused on ensuring they were able to meet the meaningful use Stage 1 attestation requirements. In addition, there was little if any experience from both hospitals and vendors with the QRDA I draft specification; and in fact, the draft specification had not yet been successfully balloted by HL7.

In addition, the requirements for participating in the electronic reporting pilot presented some major challenges to our hospital customers. The major challenges related to the volume of data required, as well as the reporting period. We anticipate customer barriers for the 2013 pilot will include lack of sufficient volume of data, inadequate collection of patient data specific to the requested quality measures, the immaturity of the QRDA standard, and the absence of a guarantee of protection of the hospital for identifiable patient health information (PHI) for study purposes.

In terms of the pilot and potentially broader roll out, we want to emphasize the amount of data that can be involved in QRDA I reporting, especially with a compressed annual reporting period. We suggest that CMS consider the option of more ongoing reporting (e.g., daily, weekly, monthly).

Is the EHR vendor's technology currently certified under the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology (HIT) Certification Program to the 2011 Edition EHR Certification Criteria? Does the vendor intend to have its EHR technology certified to the 2014 Edition EHR Certification Criteria? If so, when?

Although the EHR Association cannot comment specifically on the current certification status of our member organizations' EHRs, we actively worked with our members on comments to the 2014 draft certification test methods, prior to the receipt of the 2014 final certification test methods. We expect that our members will have their products certified to the 2014 criteria in time to allow hospital customers to attest to meaningful use during FY 2014, even though the desired timelines for certification have been affected negatively due to the availability of final specifications, test methods, testing tools, and other concerns as noted below.

As we have previously mentioned, we continue to be concerned about issues with the CQM measure specifications and value sets, the expectation that additional corrections and updates will be needed, and the untested status of the Cypress tool, test methods, and test data. In addition, vendors received updates to the 2014 edition test methods on January 16, 2013, and have since reported additional issues and clarification requests to the ONC. The EHR Association is concerned that, with less than nine months until the October 1, 2013 start of Stage 2, we continue to experience these issues. We reiterate our previous recommendations and urge that the implementation roadmap support a minimum 18-month timeframe from the date of final rule publication.

What are the top three operational challenges facing EHR vendors over the next 3 years (2013 through 2015)? Of those identified, does the EHR vendor have mitigation plans to overcome these challenges?

The acceleration and complexity of regulatory requirements have been the greatest challenges that face vendors over the past few years and potentially into the future. Given the breadth and depth of the meaningful use rules, the quality measurement criteria and associated certification requirements, providers and vendors are finding that meeting specific meaningful use requirements takes resources away from other customer-desired functionality changes and developer innovation, including areas related to usability and accountable care. The efforts necessary to implement the requirements introduced by the following three regulatory areas consume resources at the expense of addressing these customer-desired enhancements, as well as innovative advances in our software:

1. The EHR Incentive Program: Ensuring that, as vendors, we provide our customers with 2014 certified software that is thoroughly tested and available within the necessary timeframes, while at the same time addressing the potential requirements of Stage 3 of the EHR Incentive Program scheduled to begin in FY/CY 2016.
2. Electronic Quality Measurement: Based on the timeframes necessary for Stage 1 and Stage 2 of the EHR Incentive program, the development of eCQMS contained features that inadvertently resulted in inefficiencies and inaccuracies. The time pressures lead to substantial challenges and data integrity issues for eCQM specifications that we, as vendors, have had to accommodate in our software implementation. We have spent countless hours analyzing specifications and value sets, mapping clinician workflows, and providing education for our customers, as well as working with ONC and CMS on identifying errors and offering recommendations for improvement.
3. Additional Regulatory Initiatives: Developing additional software and implementation processes to ensure the ability of our customers to meet other regulatory requirements related to the implementation of ICD10, value-based purchasing, accountable care organizations, and other activities to support applicable provisions of the Accountable Care Act.

In regard to mitigation plans to overcome these challenges, as the EHR Association has stated previously, an 18-month minimum timeframe from the time we receive final regulations for the EHR incentive program, including all associated documentation, is critical to ensure that software development and implementation processes provide the most efficient, user-friendly design, while reducing any potential risks to quality care and patient safety. To the extent that the IQR program might be utilizing functionality developed for Stage 2 of the EHR incentive program, this timing is also important for the alignment of eCQMs and electronic reporting capabilities for the IQR program. Vendors must have the necessary time to develop software, perform adequate quality assurance, obtain ONC-ACB certification, and deploy the software in provider organizations. Providers must then perform internal testing and end-user training, and determine any changes needed to procedures and clinical workflow. Without the necessary 18-month time horizon, components designed to enhance quality care and safety may instead result in suboptimal workflows that could pose patient care and safety challenges.

We are concerned that the current proposed timeline for Stage 3 could also be inadequate, and refer you to our comments on the Stage 3 Definition of Meaningful Use of Electronic Health Records.

Are there any evaluation or data validation methodologies that have been used to assess the accuracy and reliability of clinical process of care quality data using QRDA category I standards?

Given the recent passage of the QRDA I DTSU and the lack of time for testing and experience from the industry overall, the EHR Association is not aware of any opportunity to explore validation methods for quality data sent via QRDA I using e-specifications for CQMs, although we agree that this work would provide much needed assurance of the accuracy and reliability of the QRDA 1 standard.

Have vendors included random sampling functionalities in currently certified systems? If yes, what guidance for random sampling has been employed, if any? If no, what barriers are presented by adding this functionality to your currently certified systems?

The Association is not aware of any specific random sampling functionality developed for currently certified systems, although specific members may have implemented such functionality. However, if clear and specific specifications are provided within an adequate timeframe, we do not anticipate any barriers at this time, but urge that vendors have flexibility in technical implementations of such functions.

In addition and as reflected in previous comments, our members support the reporting option of all patients from all payers, in order to be consistent with the current method of attribution and to simplify the reporting aspect for both providers and vendors. Providing the capability for quality measure reports using sampling methodology adds no value to our customers, as they desire the ability to view the quality measure reporting for all patients/all payers to clearly see patient level detail in order to appropriately act upon any variances. We also suggest that CMS consider allowing hospitals to report for IQR using aggregate quality measure reporting and QRDA III rather than patient-level reports using QRDA I.

As always, the EHR Association appreciates the opportunity to provide feedback on this important aspect of the meaningful use incentive program. We look forward to our continuing engagement as we work toward our shared goals of maximizing the important role that EHRs can play in the collection and reporting of clinical quality measures.

Sincerely,

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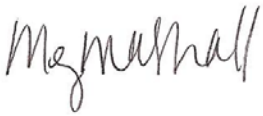

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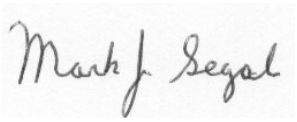

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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit http://www.himssehra.org.

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