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November 22, 2013

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

Dear Ms. Tavenner:

On behalf of the EHR Association and its more than 40 member companies, we want to alert you to a significant concern regarding the 2014 implementation of the Electronic Health Record (EHR) Incentive Program for eligible hospitals (EHs) and likely for eligible professionals (EPs), one that if not corrected could threaten the success of the program as it moves into its second stage and providers begin use of the 2014 edition certified EHR technology. We request your urgent attention and assistance given that hospitals would be affected as early as January 2014.

Electronic Submission of Clinical Quality Measure Data to CMS:
Our fundamental concern is what appears to be a material discrepancy between the capabilities and criteria to which EHR vendors developed and certified 2014 edition software for hospitals and recent, conflicting requirements issued by the Centers for Medicare and Medicaid Services (CMS). These conflicting requirements, as well as related statements by CMS staff on a recent CMS eHealth vendor call, led us to conclude that our EH customers cannot be assured that electronic clinical quality measure (eCQM) submissions using certified EHR technology will be accepted as compliant by the CMS systems receiving eCQM submissions. This situation contradicts a fundamental assumption of the Incentive Program – that a certified EHR supports all the EHR capabilities needed for a provider to achieve and report on meaningful use.

Our immediate issue stems from the posting on the CMS Quality Net website on November 14 of a "supplementary" implementation guide for the standard (QRDA-I) to be used by hospitals to submit quality measures electronically as part of

meaningful use.[1] To date, there has been no official notification to all vendors regarding this document which, per the document introduction, describes additional conformance statements (beyond those required for EHR certification) for reporting clinical quality data to the CMS EHR Incentive Program hospital electronic eCQM reporting system. We anticipate that a similar revised implementation guide will be released for EPs. Our initial review of this new implementation guide has identified changes that could require material revisions in EHR software and the need to deploy updates to customers, who in turn would face new implementation efforts and potential delays in reporting for meaningful use if such software changes are required. These variances from the certification requirements include, but are not limited to:

1. The need to create QRDA-I reports on a per encounter basis rather than per patient, as had been required for certification;
2. Rejection of null values for "any of the data elements specified in this document," a policy that modifies the previous guidance provided in the June CQM Logic Guidance Document that indicated that a "nullFlavor" could be used for "unknown" or "patient declined", which could lead to extensive rejections of meaningful use eCQM submissions as we expect that some level of null data will be unavoidable for most EHs and EPs;
3. The EHR certification number must be assigned to each QRDA submission, an entirely new data element that would need to be added to data bases and user interfaces in many cases;
4. The new requirement to include the NPI/TIN for "associated providers" when the official Data Element Catalog referenced as a standard by ONC[2] indicated that the NPI would only be required for EPs – again, a new data element with multiple implications for software development and provider usage.

We base our fundamental assumption that a certified EHR will enable providers to achieve meaningful use on the text in the ONC 2014 Certification Final Rule[3], as well as many discussions we have had with representatives from ONC and CMS. The specific excerpts from the rule are cited here:

> *"Providers who choose to submit aggregate reports will use the standard specified at § 170.205(k) (HL7 QRDA Category III), and providers who choose to submit patient-level reports will use the standard specified at § 170.205 (h) (HL7 QRDA Category I). We require that EHR technology, regardless of the setting (inpatient or ambulatory) for which it was designed, be certified to produce CQM data that could be submitted by an EP, EH, or CAH according to either standard."*

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[1] *Hospital Quality Reporting (HQR) Quality Reporting Document Architecture Category I Release 2 Supplementary Implementation Guide –Version 2.1 11/14/2013.* According to the introduction within the Guide, this document is a Hospital Quality Reporting (HQR) "supplementary implementation guide to the Health Level 7 (HL7) Implementation Guide for Clinical Document Architecture® (CDA) Release 2: Quality Reporting Document Architecture – Category I (QRDA) Draft Standard for Trial Use (DSTU) Release 2 (US Realm), July, 2012. Updated with December 21, 2012 errata (Table 17). It describes additional conformance statements and constraints for the Electronic Health Record (EHR) data submissions that are required for reporting information to the Centers for Medicare and Medicaid Services (CMS) through its Health Information Technology for Economic and Clinical Health Act (HITECH) EHR Incentive Program Hospital electronic Clinical Quality Measures (eCQM) Reporting system. "

[2] 2014 Clinical Quality Measures Data Element Catalog (DEC). Available at http://www.nlm.nih.gov/healthit/dec/ Accessed on November 13, 2013. This document is referenced at § 170.204(c) and incorporated by reference at § 170.299 in the ONC 2014 Certification Final Rule[3].

[3] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology. Final Rule. Federal Register 77: 171 (September 4, 2012) 54232.

> *"With respect to testing, we expect to approve a test procedure for this certification criterion that will* ***assess an EHR technology's ability to create data files conformant to the QRDA Category I and III standards, and upon a positive conformance assessment, verify that these data files could be accepted by CMS. If the data files were conformant and verified by the accredited testing laboratory in terms of their ability to be accepted by CMS, then the EHR technology would have fully demonstrated compliance with this certification criterion."***
>
> *"It benefits providers and CMS in that* ***each will know as a result of certification that when EHR technology is used to electronically submit a QRDA Category I or III that CMS will be able to receive it."***

Due to the changes outlined in the Supplementary Implementation Guide –Version 2.1, it appears that there are additional requirements outside of what is required in a certified system. We ask for confirmation that, notwithstanding this supplementary implementation guide, 2014 certified systems will still enable providers to achieve meaningful use, which includes electronic submission of CQMs, without further software changes.

Manual Attestation:

We understand that the Inpatient Prospective Payment Systems (IPPS) Final Rule[4] provides an option for hospitals who wish to report aggregate data for meaningful use to attest to such data on the CMS Incentive Program portal, as has been the submission approach to-date. However, we also understand that CMS continues to urge hospitals to participate in electronic submission, as stated in the IPPS Final Rule:

> *"In order to remain aligned with the Hospital [Inpatient Quality Reporting] IQR Program, and because over 82 percent of hospitals that participate in the Hospital IQR Program are already meaningful users, we strongly recommend that hospitals that are eligible to participate in both programs electronically submit up to 16 electronic clinical quality measures identified by the Hospital IQR Program in section IX.A.7. of the preamble of this final rule."*

We are not aware of any communication to the provider community 1) that attestation is now acceptable for hospital aggregate submission for meaningful use per the IPPS Final Rule, and 2) guidance as to what will be required for attestation in 2014 beyond 2013 requirements.

Since hospitals will be able to attest as early as January 2, 2014, we ask that formal communication be made on an urgent basis to the vendor and provider communities as to the availability of attestation for meaningful use and corresponding requirements. This should include updating all appropriate areas of the CMS website that today reference electronic submission of CQMs as the only option for CY/FY 2014 EPs, EHs, and Critical Access Hospitals (CAHs) beyond their first year of meaningful use participation. In light of the issues with electronic submission raised by the supplementary implementation guide, we expect that the majority of providers will be forced to manually attest to meaningful use, which would not meet CMS's goal to have this data available electronically and drive alignment between the IQR program and meaningful use.

[4] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care; Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status; Final Rule. Federal Register 78;160 (August 19, 2013) 50905.

Summary:
We note that concern has been expressed regarding the availability of certified EHR technology and the subsequent need for compressed implementation timelines by EHs and EPs. This timing is a direct consequence of compressed timing in the regulatory schedule that we have been highlighting over the past years through all available communication channels (both formal and informal). We are concerned that if the vendors are required to make the changes identified in the new guidance, these software and workflow changes would require significant additional software development, testing, and deployment, as well as implementation by our customers. Such efforts are not feasible in many or even most cases, as they would add significant new costs and time requirements to vendors and providers, and would have a material impact on providers' ability to meet meaningful use timeframes.

In summary, we ask that CMS and ONC place the highest priority on providing written clarification as soon as possible, considering that many vendors have already delivered 2014 certified software to our customers, who may have also started their Stage 2 reporting period. We also ask that CMS avoid creating a similar issue with any potential supplementary versions of Implementation Guide for Eligible Professionals. In addition, we ask for attestation education and guidance to be made available as soon as possible for the provider community. More generally, we urge CMS to formally ratify the widely held expectation, grounded in the ONC and CMS Final Rules, that use of certified EHR technology is sufficient for ensuring providers that electronic CQM submissions can be generated and accepted by CMS for the EHR Incentive Program.

Sincerely,

Michele McGlynn
Chair, EHR Association
Siemens

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

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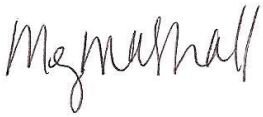

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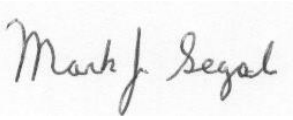

Mark Segal
GE Healthcare IT

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 the Healthcare Information and Management Systems Society (HIMSS). For more information, visit www.ehrassociation.org.

CC:
Patrick Conway, M.D., Deputy Administrator for Innovation and Quality and Chief Medical Officer, CMS
Jodi Daniel, Director of the Office of Policy Planning, ONC
Kate Goodrich, M.D., Director, Quality Measurement and Health Assessment Group, CMS
Elizabeth Holland, Director, HIT Initiatives Group, Office of e-Health Standards and Services, CMS
Aryana Khalid, Chief of Staff to the Administrator for the Centers for Medicare & Medicaid Services
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