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August 27, 2014

Kevin Larsen, MD
Medical Director of Meaningful Use
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Minet Javellana
Government Task Lead
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

Dear Dr. Larsen and Ms. Javellana:

On behalf of the Electronic Health Record Association (EHRA), and specifically the Quality Measurement Workgroup, we want to thank you for requesting our input on options for the proposed content and timing of the next releases of the Cypress clinical quality measurement (CQM) certification tool. This includes several options to better align Cypress with both the annual release of the CQM specifications and updates to the Quality Reporting Document Architecture (QRDA) Implementation Guides. We want to take this opportunity to summarize the feedback we have previously shared in calls and meetings, as well as to reiterate several open questions we see as critical in determining the best path forward.

Backward Compatibility of Cypress Versions

The first question raised by ONC and CMS is on the importance of backward compatibility within Cypress, and whether it is important for one installation of Cypress to be able to accommodate multiple versions of the CQM specifications. Alternatively, is it reasonable to address this capability by installing multiple Cypress versions in order to certify CQMs using previous versions of the quality measure specifications? The general consensus of EHR developers is that, while it is important that certification be available for older CQM specification versions, we generally agree that it is reasonable to install an older version of Cypress for this purpose. For example, some vendors intend to certify additional eligible professional (EP) CQMs later this year (in 2014) using the June 2013 measure specifications so these measures can be reported this year. It also seems reasonable that Authorized Testing Labs (ATLs) will keep multiple Cypress versions available to use for testing and certification

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purposes. Therefore, although nice to have, we give low priority to backwards compatibility within one version of Cypress.

Alignment of Cypress with CMS QRDA Implementation Guides

A second question is on the priority of alignment between the Cypress CQM certification tool and the Centers for Medicare and Medicaid Services (CMS) QRDA Implementation Guides. Certification provides assurance to an EP or eligible hospital (EH) that the certified software can be used to successfully meet meaningful use program requirements, including the submission of CQM data to CMS, so the persistent discrepancies today between the Cypress CQM certification tool and CMS QRDA Implementation Guides are a serious concern. These discrepancies were first escalated by EHR developers in March 2013 (in stakeholder meetings at HIMSS and in [JIRA tickets](#)); and a [formal letter was written by the EHR Association to CMS](#) on this topic in November 2013. This issue persists in August 2014, with no clear path to align certification with CMS requirements.

In the short term, Cypress should continue to correspond to the previously published certification criteria. But, as suggested on a recent Cypress Tech Talk call, it would be useful to offer optional testing criteria to meet the CMS QRDA Implementation Guides.

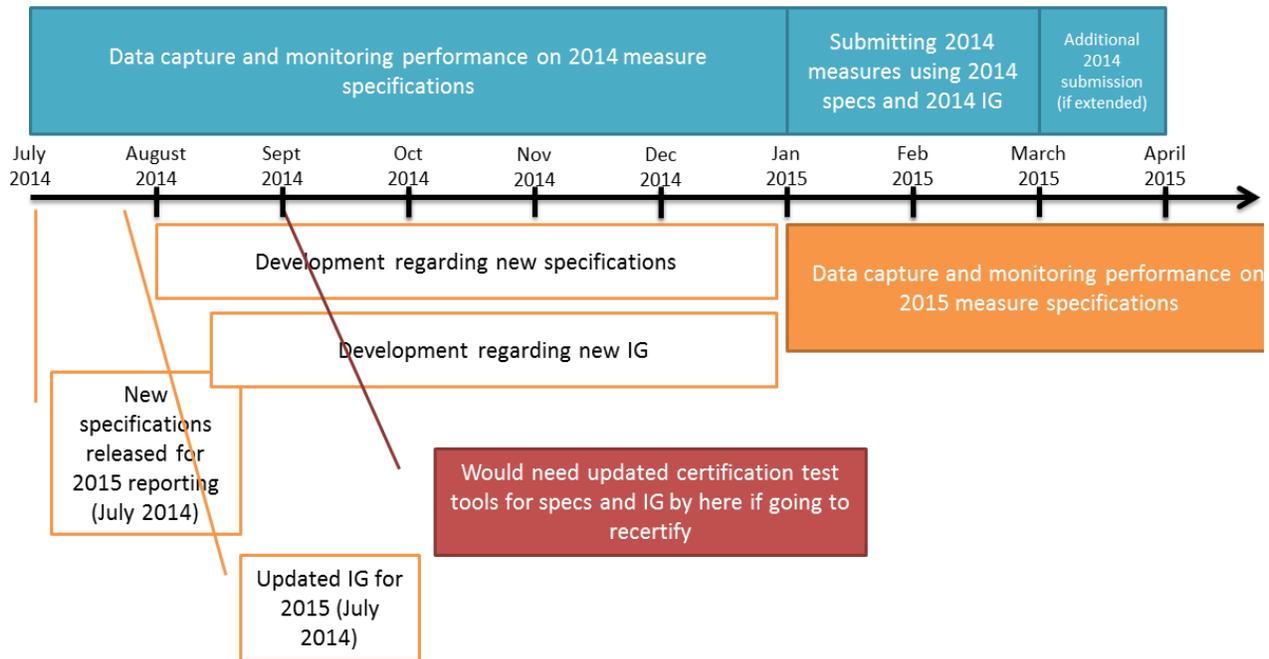
CQM Specifications, Updates, and the Need for Recertification

Finally, despite provisions in recent hospital and physician proposed and final payment rules, there remain pressing questions around the timing of measure specifications and the corresponding updates, as well as clarification and agreement among all stakeholders, including CMS, ONC, Authorized Certification Bodies (ACBs), and ATLS on whether certification is or is not required for the annual updates.

The 2014 annual CQM update for 2015 reporting was released for EH measures in April 2014, and for EP measures in June 2014 (with additional updates in July 2014 to correct errors in the original publication). These updates contained significant revisions to both the CQM specifications and the value sets to correct errors and harmonize the value sets. In addition, the new 2015 combined QRDA Implementation Guide was published at the end of July 2014. Given the extent of the updates, this cadence does not leave sufficient time to ensure implementation by providers prior to the beginning of the measurement year. For example, for EPs this leaves only five months for development, release, and implementation of updates if EHR developers wish to make the software available prior to the beginning of the 2015 reporting periods. However, EHR developers are hesitant to begin this work when CMS has indicated they will not be able to accept 2015 specifications for the 2014 reporting year, and EPs might still be attesting for the 2014 reporting year through February 2015.

It also remains unclear to EHR developers if updates to the new annual measure specifications and Implementation Guide will require recertification. Recertification causes delays in the delivery of the updates to our customers, as well as requiring significant resources and additional expense in the development process that discourages keeping current with CQM specifications. While CMS has now stated in the final IPPS rule that certification of the EH annual measure updates is not required, and made a similar proposal in the Physician Fee Schedule (PFS) proposed rule for 2015, EHR developers have heard conflicting expectations from certification and testing bodies. In addition, removing the requirement to certify the EP annual measure updates is only proposed in the PFS proposed rule, which will not be finalized until much later in the year. This creates uncertainty and concern that EHR developers will have too little time to accomplish certification and subsequent implementation of software by eligible providers.

If certification is required, the certification tools must accommodate the new requirements with sufficient advance notice to permit development and certification of all products. If updated certification tools are not available by September 1, 2014, we are concerned that certification testing labs will not have sufficient capacity to process certifications in the time allowed. The graphic below illustrates this timing challenge.



Additional clarification is needed concerning any requirements to recertify measures that were previously certified because of changes to Cypress versions. For example, when one of our members recently certified a set of additional CQMs using the 2013 version, they were also required to *recertify* 2013 CQMs that had been certified previously, with the rationale that the original CQMs had been certified using a previous version of Cypress, and so must be retested using the latest version.

EHRA Recommendations

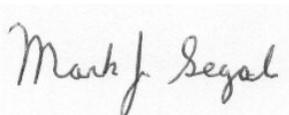
EHRA appreciates the current efforts by CMS and ONC to improve the annual measure update process, and we are hopeful that the results of our collaborative work will improve the process for next year. We also appreciate the response to our concerns and recommendations in both the Inpatient Prospective Payment System (IPPS) and PFS rule-making process. The recommendations made in our meetings with CMS and ONC, as well as in this letter, will contribute to a greatly improved process for all stakeholders. To summarize, the EHR Association has made the following recommendations:

- Moving forward, harmonize the Cypress tool and CQM certification requirements with the CMS submission requirements, including the CMS QRDA Implementation Guide(s). But, for Stage 2/2014 edition, only require that Cypress test for published certification requirements, with optional additional test criteria available for conformance with the CMS specifications.
- Allow for the timeline constraints and simplify the annual CQM update process by considering the following recommendations:
 - Limit the annual between-final rule CQM updates to “non-substantive” changes as stated in the regulations, and work with stakeholders to define the appropriate definition of “non-substantive”;
 - Ensure more thorough testing of new CQM specifications prior to inclusion in a federal program; and,
 - Determine an alternate method and timeline to “substantive” changes.

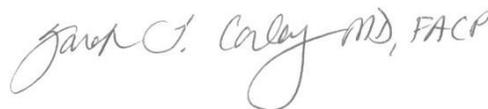
- Ensure that there is alignment between CMS, ONC, and the ATIs regarding not requiring certification for the annual updates, as stated in the recent IPPS final rule, and proposed in the PFS proposed rule.
- Ensure there is clarification on the need to recertify previously certified measures due to a modification made to the Cypress testing tool.

We appreciate your attention to our concerns, and we look forward to working with you as we continue to improve the CQM process.

Sincerely,



Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

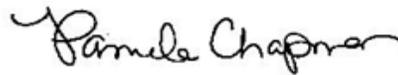


Sarah Corley, MD
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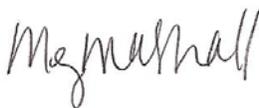
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About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 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.

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