Office of the National Coordinator
Health IT Policy Committee
Certification Hearing
Washington, DC
May 7, 2014

Testimony by:
Mickey McGlynn, Siemens
EHR Association, Chair

HIMSS Electronic Health Record Association

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EHR Association Testimony, Mickey McGlynn – May 7, 2014

My name is Mickey McGlynn, with Siemens Healthcare and the Chair of the Electronic Health Record Association, for whom I am speaking today. Thank you for giving us this opportunity to talk with you.

Recognizing that certification is intended to ensure that EHRs meet the standards and certification criteria to help providers and hospitals achieve meaningful use, we understand how important certification is to our customers, and thus to the vendor community in support of our customers.

And while the obvious benefit of such a program is to enable providers to meet the requirements of meaningful use and the growing number of programs and reimbursement models that might be based on the use of certified technology, the real benefits of such a program should accrue to providers and their patients in the form of higher quality, more efficient care delivery.

From a vendor perspective, though achieving certification and gaining our customers' confidence that our products meet the meaningful use requirements are important results, our primary goal is to produce high-quality software that meets a broader set of our customers' needs, only some of which relate to the meaningful use program or those defined by the ONC certification programs.

As currently defined, the processes, deliverables, and tools for certification, although very well-intended, are not effectively enabling EHR suppliers to fully achieve their goal of developing software that meets their customers' priorities, encourages innovation, and ultimately serves the patient-centric objectives of the meaningful use and certification programs. Our concerns about these issues are well documented in various letters and meetings with ONC over the past two years. There is not time today to go through all of the specifics called out in these letters. I have included them as part of our submitted remarks so they are available for your review.

Specific examples of our experiences include:

- First, the full set of requirements is not provided with adequate time for development. The full set of requirements is based on the information in the final rules (both certification and meaningful use) the test scripts, FAQs, CMS specification sheets, and is even impacted by the testing tools and test data. And, as they become available, we have multiple examples that show that these deliverables have added and changed the requirements as defined in the initial certification rule. This causes significant waste as we try to reconcile these documents and incorporate the new requirements into our software, ultimately impacting the quality and usability of the software. In addition, it causes delay in when certified software becomes available in the market, which is a concern for all stakeholders.
- Second, the certification criteria for the meaningful use objectives, the reports that measure these objectives, and the clinical quality measures, are not consistently aligned with each other and sometimes not aligned with clinical practice. We are concerned that, as the provider community comes to use the software, there will be dissatisfaction that will reflect negatively on EHR developers, when in fact we are doing what is required for certification.
- Lastly, the testing tools and associated data are not properly tested before they are rolled out for use by the vendor community.

There are a number of opportunities to improve the certification program for all key stakeholders while also maintaining the integrity of the program. We have documented our recommendations to ONC in the past in the letters and discussions I mentioned. I will highlight a few now:

- All of the materials that impact the requirements must be available much earlier, ideally concurrently with the release of final rules, and remain stable. Or, the overall timeline for the program needs to accommodate when the information becomes available. You can look at any good software development methodology and it will tell you that before you begin to develop software, a complete and stable set of requirements is needed, and developers must understand how the software is going to be tested and used.
- Reduce the overall complexity of the roll-out of the program. The program is incredibly complex, including a large set of complex requirements, multiple documents available in multiple locations, different tools to track issues, and with no schedule as to when new information can be expected. In a recent meeting that included vendors, ONC, and CMS, the topic of complexity was discussed and there appeared to be broad alignment then that the program is, in fact, too complex.
- We strongly recommend the use of a Kaizen process to support an effective review of the certification program, considering our recommendations and experiences as well as those of all stakeholders. This approach has been used in other HHS programs with good results. The Kaizen process should be organized around key elements of the certification process - including all criteria impacting certification, test methods, testing tools, testing and certification processes, specific issues associated with quality measures, and documentation/FAQs. A Kaizen process focuses on eliminating waste, improving productivity, and achieving sustained continual improvement in targeted activities and processes. Participation in Kaizen events requires significant commitment from all involved. However, we strongly believe that the opportunity for improvement fully justifies the time and effort needed to prepare and participate in these events. EHRA commits this time and effort.

We recognize that certification has an important role in the health IT industry today and look forward to working with you to enable it to achieve the desired goals in a way that is efficient and effective.

Thank you.

Addendum 1: EHR Developer Perspective: Certification Processes and Deliverables

The following description of EHR certification processes and deliverables is presented to assist regulators and other stakeholders fully understand vendor workflows required to support development and delivery of certified EHR technology (CEHRT). The following discussion focuses on work driven by these regulatory initiatives and our experiences working with the tools and resources provided to us.

Notices of proposed rulemaking (NPRMs) are EHR developers' first opportunity to begin planning software design and development work which is then refined by the final rule.

- CMS NPRM, EHR Incentive Program, Stage 2
- CMS Final Rule, EHR Incentive Program, Stage 2
- ONC NPRM HIT Standards, Implementation Specifications and Certification Criteria, 2014 Edition
- ONC Final Rule HIT Standards, Implementation Specifications and Certification Criteria, 2014 Edition

Once the final rules are issued, the following list defines the information currently required to begin the development of functionality required for meaningful use (MU). Information can be found across several organization websites. The list below does NOT include approximately 40 referenced standards documents or implementation guides associated with the certification criteria. Each required standard and implementation guide must be researched independently and incorporated into the development process.

- **www.Healthit.hhs.gov is used for gathering the following information:**
  - NIST Draft Test Procedures
    Proposed test procedures and test data for 2014 Edition were released in seven waves between September and November.
  - **2014 Edition Test Method once drafts are finalized**. The following information is essential to assimilate interpretation of the certification criteria in order to successfully achieve certification:
    - Test Procedures for each criterion (approximately 40) with revision dates when criteria are changed.
      - Standards specifications (approximately 40 associated with adopted criteria are not included in the Test Procedures)
      - Implementation Guides (approximately 10 associated with adopted standards are not included in the Test Procedures)
      - Test Data is required for each criterion, with revision dates if/when changed.
    - Validation Testing Tools as required for test procedures must be available and functioning, included here with hyperlinks to NIST testing validation tools utilized for 2014 Edition Test Procedures:
      - Direct Certificate Discovery Toolkit
      - Transport Testing Tool includes C CDA, Direct and SOAP
      - Electronic Prescribing Validation Tool
      - Laboratory Results Interface (LRI) Validation Tool
      - Electronic Laboratory Reporting(ELR) Tool
      - Cypress Testing Tool
      - Immunization Information System Validation Tool

  - Syndromic Surveillance Reporting Validation Tool
  - HL7 Cancer Registry Validation Tool

- Note that testing tools frequently impose requirements beyond those mandated by the regulations, adding to the development effort.
- Test Data used exclusively for validation Testing Tools. These datasets are stored within the testing tool hyperlinks and may include multiple use cases per testing tool.
- All revision dates for data or tool versions must be accessed through the test procedures to determine updates as no revision history is currently available.
- Google groups to support tools and/or additional standards, with support groups for submitting questions (available as hyperlinks).
- Automated Numerator Recording (g)(1) and Automated Measure Calculation(g)(2) are listed in the 2014 Edition as criterion. However, the single criterion includes *all* objectives requiring percentage calculations and extensive additional specifications within the criteria.
- Test Procedures specifying Numerator, Denominator, Exclusions calculations for (g)(1) and (g)(2) may require multiple procedures when Stage 1 and Stage 2 criteria are calculated differently.
- Test Data for *each* objective requiring calculation. Each objective requires extensive pre-entry of patients and data from the five datasets provided to check each calculation for accuracy during testing.

- **Electronic Clinical Quality Measures (eCQMs):** The process to certify the eCQMs is extensive, and includes additional websites and documents.
  - The Quality Data Model (QDM) definitions must be reviewed in order to determine any additional requirements on the QDM site.
  - Monitor CMS.gov CQM site for the measure specifications which are not released at the same time as the CMS and ONC final rules.
  - Hospital and ambulatory e-measures:
    - Meaningful use allows the use of December 2012 specifications (value sets and eMeasure versions). However, Cypress was updated to require the April 2013 version for EHs and the June 2013 version for EPs, requiring vendors to implement the latest version of the eCQMs they did not certify prior to the release of the new measures. The new versions of value sets and measures were available but there was confusion regarding timing and as to whether vendors needed to use them for certification.
  - CMS.gov eCQM Library – Download eCQM measure specifications and measure logic guidance documentation.
  - Value Set Authority Center – download value sets.
  - AHRQ USHIK site – Use this site to download different formats of the measure specifications and value sets.
    - Value sets for associated measures
  - Cypress Project page – used to download the Cypress tool, test data, and associated documents needed to implement the tool locally, in order to test the eCQMs prior to certification itself.
  - Monitor the Cypress Google Groups: Announcements and Talk.
  - Monitor the QualityNet eSubmission Pilot site for additional guidance.
    - QRDA 1 and QRDA 3:

The QRDA formats require the "version specific identifier" and "version neutral identifier". CMS directed users to the e-specification navigator which is no longer available.

- Review and monitor the JIRA support tool to address problems with Cypress versions, measures, and data - JIRA Issues Tracker
  - Validation testing tool configuration, Cypress:
    - New versions of the Cypress tool addressed reported problems, although the version number was not always updated. New versions also required more current versions of the measures and value sets so vendors need to be diligent about downloading versions of the testing tool (even when the version number did not change) in order to make sure they were working with the same testing software as would be used during certification.
  - JIRA support tool to address problems with Cypress versions, measures, and data vendors enter any issues and/or questions into the JIRA support tool.

- **ONC Certification FAQs**
  Vendors rely on information provided during the CMS/ONC Vendor workgroup calls, Certification FAQ and individual email responses. Many questions are responded to individually via email and not available to the majority of vendors unless considered as a FAQ. EHRA continues to request a transparent process to enable all vendors' access to complete information.

- **ONC CHPL- Certified Product List**
  Vendors utilize this information to address providers' questions regarding certification status and attestation requirements.
- **www.CMS.gov**
  This website provides a number of tools which are essential to understanding CMS' interpretation of the final rules.
- **CMS FAQs for EHR Incentive Program**
  Questions are submitted on a one-by-one basis to address intended meaning associated with criteria. The capability to search for topics and keywords exists, but website improvements could make it easier for vendors to track revisions and updates.

- **Vendor Technical Specification Sheets for each Hospital and Ambulatory Objective, includes:**
  - Definitions
  - Measure descriptions for each MU stage
  - Measure English statements for numerator/denominator/exclusions per measure (could be multiple) and MU stage (could be multiple)
  - Measure elements for numerator/denominator/exclusions per measure (could be multiple) and MU stage (could be multiple)
  - CMS final rule references
  - Additional Information on the objective/measure (may include FAQs)
  - Certification and standards criteria

  These technical sheets are essential to development and interpretation of MU certification criteria.

- General categories of information on www.cms.gov are often used by vendors to answer provider questions are essential to accompany certified products (e.g., registration and attestation, MU Stage 2, audit information, vendor workgroup information, tip sheets.)

- **ONC ACB and ATL Information**
  In order to apply for and complete certification, each vendor requires the following deliverables from their chosen testing and certification body:
  - Certification and testing application
  - Certification program agreement
  - Self-attestation forms including any specific ONC requirements for documentation of specific criteria
  - Certification Program Handbook
  - Test scripts developed by the testing laboratory identifying expected results based upon testing body interpretation of NIST Test Procedures
  - ATL and ACB FAQs specific to test scripts and certification expectations for all criteria undergoing testing
  - ATL and ACB updates or webinars regarding specific testing requirements as the process evolves prior to testing and certification, ATL must incorporate ONC and CMS FAQs new versions of NIST Test Procedures, Test Tools, and Test Data into ATL and ACB Test Scripts.
  - Testing body-hosted conformance validation testing tools **must** be aligned with NIST validation testing tools versions, and versioning to accommodate vendors in the process of testing preparation. Testing tools are often updated and previously successful testing conformance fails.

Addendum 2: Previous correspondence with ONC regarding the certification program

ONC Issues for EHR Association 2014 Edition Letter – February, 2012

February 15, 2012

David Muntz
Judy Murphy
Jacob Reider, M.D.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Dear Mr. Muntz, Ms. Murphy, and Dr. Reider:

We appreciate that ONC and CMS have acknowledged the essential role that EHR developers play in the health IT community, and we recognize and appreciate the hard work and collaboration of ONC team members as they work to achieve success for the HITECH program. The EHR Association is committed to working collaboratively with ONC and CMS in support of HITECH and our mutual goal of enhancing the quality and efficiency of care provided to patients and their family members.

In this spirit of collaboration, and specifically to resolve what are evolving into serious challenges to the successful accomplishment of the objectives of the meaningful use incentive program, representatives from EHR Association member companies have contributed to the development this letter, as well as a more detailed list of example issues sent to you under separate cover titled *EHR Association Vendor Reported Errors with ONC Testing Procedures and Tools*.

Below we address multiple topics spanning many aspects of the EHR incentive program. These comments are offered in the spirit of collaboration and recognition of our shared objective to help the nation's healthcare professionals and hospitals succeed in their pursuit of meaningful use and its intended benefits. We note that we are already working collaboratively with members of the appropriate teams at ONC to address some of the issues identified here and will continue to do so.

We have divided this letter into two sections. Section 1 is focused on issues that require immediate resolution to enable us to move forward to create, certify, and deploy 2014 certified EHR technology (CEHRT). In the absence of timely and definitive resolution of these issues, many vendors are being forced to take alternate approaches to meet requirements, such as sub-optimal workflows, hard-coding, or not certifying for certain criteria Section 2 focuses on broader issues, many of which are the root causes of the immediate issues identified in Section 1, and therefore also in many cases require urgent resolution as well to mitigate the current problems and to avoid delays with future efforts.

Section 1: Resolution of Issues Impacting 2014 Certification

With the earliest possible 2014 reporting period for meaningful use scheduled to start in roughly eight months, and many hospitals and eligible professionals wanting to start their efforts related to use 2014 certified products to meet Stage 1 and Stage 2 requirements, we must have clean, final, and validated versions of the following:

- Clinical quality measure specifications and value sets;
- Rapid resolution of outstanding questions regarding 2014 certification criteria;
- Certification test procedures;
- Certification test data;
- Functioning, validated, and usable certification test tools, including the interoperability transport tool, the Cypress tool for quality measures (see discussion in Section 2), and all others as identified by test procedures;
- Consistent understanding and agreement between ONC, testing labs, and ACBs on all of the above;
- Answers to FAQs that have been submitted through multiple official channels on the above and other issues related to certification and meaningful use as it; applies to product development and certification.

To accomplish these objectives, we respectfully but urgently request the following:

1. **Questions on certification submitted to ONC (onc.certification@hhs.gov)**

- As discussed with ONC leadership, a response to all questions submitted to date by February 18.
- One week turnaround on all questions submitted through designated ONC channels moving forward.
- Transparency to all developers and other stakeholders:
  - Submitted questions should be posted, along with their status.
  - Answers to questions should be made public as FAQs or otherwise.
- Providing the answer to only the submitter does not enable the community as a whole to learn from the response and leads to industry inefficiency by forcing other vendors to submit the same questions and ONC to answer them multiple times.

2. **Questions submitted on waves of test procedures and test data**

- Although we have been told that ONC does not consider the test waves to have been issued for official public comment and thus they do not require ONC responses, in the spirit of working together to achieve the results of the program, we ask that you respond to the questions that were asked in our detailed responses to all seven waves of the test scripts, especially those that seek clarification on provisions retained in the final test methods.
- Each test procedure with an associated testing tool has a unique question submission process managed by NIST using Google Groups. As with the questions to ONC, we ask for responses to the questions submitted via the NIST and ONC processes on the various testing tools by February 18, and a one-week turnaround on all issues submitted moving forward.

3. **Transparency to expected publication dates of each key certification-relevant deliverable, including certification test data, test methods, testing tools, and clinical quality measure specification revisions**

- *We ask that ONC publish a schedule for updates to test methods and other key certification and standards-related documents so that EHR developers know how to plan and manage development resources and schedules*. As an example of why such a schedule is needed, on January 16, 2013, new versions of certain test data and test methods were released. Many developers had already started entering data for testing, so this new information immediately created rework and schedule changes, requiring unanticipated work by many staff in some cases. Although we appreciate that the updated test data and test methods addressed some issues that our members submitted, we could have planned more effectively if we had known when to expect those updates. Even being told a week ahead of the release that new information is coming out would allow us to allocate our resources more effectively.

- *Consistent weekly communication from ONC about all changes to deliverables identified above.* We need one consistent way to understand the changes being made to the various deliverables and answers to FAQs. Most developers are far along in the software development process for their 2014 edition(s), and we need access to "one source of truth" for certification-related information, including clear change tracking. Unfortunately today, developers must search for information and identify for themselves where and when information has changed. Having to track multiple communication channels with multiple points of contact, including separate Google Groups channels for each NIST-maintained test tool, adds an additional layer of complexity to an already complex program. We request that this change management process be coordinated through ONC with one summary of all of the changes published weekly by ONC.

We recognize that the above requests span multiple organizations within ONC, CMS and the broader Departments of Health and Human Services and Commerce that have responsibilities for supporting the certification program. From an end-user perspective, however, focusing on the developer community and the providers that we serve, the EHR incentive program is a single program. For our development staff, the focus is on achieving certification, not focusing on each sub-component of the certification process. Given this reality, the existence of different organizational responsibilities among federal government agencies should be transparent to developers and not result in siloed channels of information.

We note that the JIRA tool released by ONC and CMS for tracking clinical quality measure issues is an excellent approach to more effective and transparent communications. We thank you for implementing this tool for the quality measures portion of the program and request that this single tool (or a similar tool if JIRA is not appropriate) and its associated processes be applied more broadly to all stakeholder questions regarding certification. Such a tool and process will help developers working toward certification to better manage resources and schedules, so they in turn can set the right expectations with their provider customers about when certified EHR technologies will be available. Ultimately, providers need this certainty to better manage their resources, and to safely and effectively implement and test new software.

Section 2: Broader Issues

In addition to the very time-sensitive issues outlined above, we have been discussing the following broader points with ONC since 2010, and believe that they remain largely unaddressed. Their resolution relates directly to the time-sensitive issues raised above, including their root cause mitigation, and prevention of such issues in the future.

- In order to avoid unintended and potentially severe consequences for provider workflow, patient safety, and/or delays in EHR delivery, certification criteria and test scripts should be developed through an open, iterative process that accommodates early feedback by industry experts (e.g., hospital providers and eligible professionals utilizing EHRs, experienced EHR developers, etc.). We proposed earlier working together on Stage 2 requirements to move this process forward, but we were not sought out for input in the development of the certification criteria or processes. We note that, not only are the FACA and NPRM comment processes not the most productive venue for ONC-developer collaboration, but that much of the certification criteria and test method work seems to have been done by consultants outside of the transparency of FACA oversight. How can we change this process moving forward, so that both informal and formal inputs from EHR developers, who have substantial experience with certification, inform these processes? We offer recommendations:

    - First we should build on our experiences to-date to create a multi-stakeholder process during the development of Stage 3 certification criteria that is similar to the process used to develop the Meaningful Use Matrix, including multiple public comments periods and opportunities to ask for clarity, as well as focused discussions with and inputs from developers. We suggest that ONC and NIST adopt similar processes.
    - Second, we ask that ONC change the criteria development process to ensure that there is more certainty sooner, allowing improved planning sooner for both developers and providers, with a detailed multi-year road map for meaningful use and certification criteria.
    - Finally, as we requested regarding Stage 2, Stage 3 meaningful use and 2014 edition certification criteria should be finalized (i.e., in a final rule) 18 months before the start of a meaningful use eligibility period, with associated materials such a test methods, meaningful use specifications and CQM specifications, available much sooner after the final rules are issued by ONC and CMS.

All of the above recommendations are offered with the goals of saving valuable time for all parties and producing a higher-quality result at the end, including more efficient deployment, training, and quality testing processes on-site with our clients. The fact that this 18-month period has not been implemented – is, in our judgment, a significant contributing factor to the many open issues we have today. Some recent examples which highlight our concerns and where we see opportunities for improvement are identified below.

Certification Test Data, Test Methods

The EHR Association provided ONC with detailed comments on proposed test data and test methods for each wave of the scripts as they were released. We spent many hours engaging member representatives in detailed discussions to develop our recommendations. We compiled questions from many EHR members, asked for clarification on a number of test procedures, and specified a number of issues with the test data. We assumed that these comments would be addressed in detail by ONC, but to date, even after two revisions to the drafts, there are still a number of unanswered questions.

- Prior to ONC's release of 2014 Edition Drafts, we requested an in-person workshop to present issues that we found with draft test methods after their release in an attempt to expedite

resolution of open questions, with the goal of finalizing more accurate test methods that would enable software development based on complete, accurate, validated, and usable information. We made that request ONC in April, 2012 and did not receive a conclusive response.

- ONC presented its certification "Technical Workshop" in November. Unfortunately, this session did not provide a meaningful opportunity to engage with ONC in an interactive fashion on outstanding issues, but rather focused on a presentation of the certification process. During the workshop, ONC staff summarized some of the comments submitted on draft test procedures, but most of the comments we submitted were not acknowledged. ONC stated during this meeting that the comment period on the seven waves was not an official public comment period (as would occur with an NPRM) and, as such, ONC was not required to address all the comments and would not do so.
- To date, we have not seen documentation from ONC regarding those comments. We submitted these comments, as requested by ONC, because they represented areas of concern or confusion for the developer community and, as called for in Section 1, ONC provision of this information would still be of great benefit to developers, especially for comments or questions that are relevant to the final test methods. We also note that there was no change tracking between the draft test methods and the initial versions of the final test methods, requiring extensive and duplicative work by developers to understand what changes were needed to planning and development work already completed.

Remaining issues continue to be sent to ONC by EHR Association members via email with, in general, no acknowledgement of receipt or response. There have been a few ONC FAQs issued to address some concerns, but the majority of the Stage 2 certification issues remain unaddressed. We appreciate the recent focus on improving the turnaround time and setting a specific timeframe for responses (one week), and look forward to seeing the responses to all questions submitted to date this week.

Cypress Testing Tool

We remain concerned that the current quality of the Cypress Testing Tool is insufficient for use in product certification, and thus recommend that the use of the Cypress tool for certification of the CQMs required for 2014 edition software should be optional until outstanding priority issues are addressed. In a letter dated January 22, 2013, we outlined specific concerns with Cypress and made a number of recommendations. We have also provided a detailed list of Cypress issues as part of a document sent to ONC called *EHR Association Vendor Reported Errors with ONC Testing Procedures and Tools*. We greatly appreciate the initial response received from ONC to this letter and are reviewing it.

Usability

ONC promoted a Usability Workshop held at AMIA in November 2012 as an opportunity to address questions and confusion over application of usability testing and reporting of usability findings in the 2014 certification process. Unfortunately, no new information was provided at the workshop, and outstanding questions were not resolved. Specifically, there are two outstanding questions regarding user- centered design (UCD) certification requirements which were asked during the workgroup call last fall, submitted in writing to ONC in October, and asked directly again at the AMIA workshop in November.

First there is a conflict between the ONC Certification and Standards Final Rule and the test methods document. The Final Rule says that earlier versions of software may be used if evidence of summative

usability testing can be provided. The test method states that the current certified version of software must be used for such testing. We request a definitive answer as soon as possible.
Second, uncertainty remains as to how developers can assert what UCD process was used in developing legacy systems that remain in use but for which the original design intent and process is not known. We request definitive and urgent clarification of what can be submitted and considered acceptable.

During the November 28, 2012, EHR Association afternoon meeting with ONC, CMS, and other government stakeholders, Association participants presented our collective view that neither the Technical Workshop nor the AMIA Usability Workshop addressed the certification-related issues that we had raised and we expressed concern that clarification was still needed on several topics so that developers can effectively proceed with software development and preparing for certification testing. However, these questions have largely gone unanswered.

We thank ONC for all of your efforts. We offer these comments in the spirit of cooperation and collaboration and eagerly await your earliest reply.

Sincerely,

/s/

Michele McGlynn
Chair, EHR Association
Siemens

/s/

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

/s/

Jason Colquitt
Greenway Medical Technologies

/s/

Lauren Fifield
Practice Fusion, Inc.

HIMSS Electronic Health Record Association

/s/

Charlie Jarvis
NextGen Healthcare

/s/

Meg Marshall
Cerner Corporation

/s/

Ginny Meadows

/s/

Mark Segal

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.

Cc: Rob Tagalicod, Director, Office of E-Health Standards and Services, CMS
Elizabeth Holland, Director, HIT Initiatives Group, CMS
Rob Anthony, Specialist, Office of E-Health Standards and Services, CMS
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Gail Arnett, Senior Director, Corporate Relations and EHR Association, HIMSS

HIMSS Electronic Health Record Association

EHR Association Cypress Letter – January, 2013

January 22, 2013

Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health & Human Services (HHS)
355 E Street, SW, Suite 310
Washington, DC 20024-3221

Dear Dr. Reider,

As we strive to implement the most recent versions of the clinical quality measures (CQMs) and value sets (with updates just released on December 21st, 2012), and to understand and prepare for the requirements for certification of the CQMs, EHR Association members are collectively very concerned over the current status of the Cypress testing tool, test procedures, and test data. We feel strongly that these issues threaten the successful CQM certification of our EHR products, and the ability for us to provide 2014 Edition EHR software to our customers within the necessary timeframe.

We were hopeful that the vendor webinar held on Thursday, January 11th, 2013 to demonstrate the Cypress testing tool and conduct a Q&A session would help to answer some, if not all, of our questions and concerns. Unfortunately, our expectations for an open and collaborative dialog and information on planned resolution of the many issues identified were not met.

The attached document provides very specific details regarding the issues we have found with the Cypress testing tool, its functionality, and related data sets and test cases.

- We are concerned that the current quality of the Cypress Testing Tool is insufficient for use in product certification, and thus we recommend that the use of the Cypress tool for certification of the CQMs should be optional for 2014 Edition EHR certification until the issues are resolved. In the attached detailed document, we describe specific concerns and make a number of recommendations.

- If ONC and CMS require the use of this tool, we ask that they fix the identified errors in the tool and the test data, and employ a thorough quality assurance, validation process to ensure its readiness as a test tool for use with a large number of EHR technologies.

- We also ask that ONC and CMS provide a written plan to maintain the tool, including test data, validated with new and revised measure specifications. The EHR Association also asks for specific responses and suggested resolutions to the additional issues included in the attached detail document on this topic.

In the spirit of collaboration and in support of open dialog and transparency, we respectfully request a response from ONC on their plan to address these issues within the next five business days, and will make EHR leadership and subject matter experts available to participate in discussion and resolution of these issues.

Sincerely,

/s/

Michele McGlynn
Chair, EHR Association
Siemens

/s/

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

/s/

Jason Colquitt
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Lauren Fifield
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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.

EHR Association Cypress Testing Tool Recommendations – January 2013

The EHR Association understands and agrees with ONC's efforts to ensure that EHR solutions are tested for accuracy in the calculation of clinical quality measures (CQMs), and looks forward to working with ONC to support this goal. To that end, and to assure our customers that the revised test procedures achieve the goal of accurate clinical quality reporting, each component of the quality measure testing process, including automated tools, must be thoroughly validated. In particular, the Cypress Testing Tool should undergo thorough accuracy testing prior to incorporation in the ONC certification test process.

Overarching Issues with and Recommendations for the Cypress Testing Tool

1. We are concerned that the current quality of the Cypress Testing Tool is insufficient for use in product certification, and thus we feel that the use of the Cypress tool for certification of the CQMs should be optional at this time for 2014 Edition EHR certification, until the following issues are addressed.
   - The tool has not been fully tested using real-life data and testing scenarios.
   - We do not feel confident that the use of the tool in its current state will ensure consistent, accurate CQM calculations and reporting across each and every vendor EHR product.
     i. Certification must be consistently accurate in order to ensure that the process is equitable across all vendors.
   - The tool, test procedures, and data sets place undue burden on EHR vendors and require testing functionality that is not required by meaningful use and has no market value.
   - There is no clear plan to keep the tool updated with the evolving specifications

2. If ONC and CMS require the use of the tool, we ask them to:
   - Fix the identified errors in the tool and the test data, and validate it as a test tool;
   - Provide a written plan to keep the tool, including test data, validated with new and revised measure specifications;

   Provide a response and suggested resolution to the additional issues listed below.

Detailed Cypress Issues and Suggested Resolutions

1. Cypress test procedures require EHR technology consumption of test patient records during the test process. This step must be done either by import of QRDA Category 1 format files or, because CEHRT does not include the requirement to import QRDA1 into the EHR itself, manual entry of HTML-formatted test patient files.

   a) Due to the fact that the QRDA import by an EHR was not a requirement for certification for a complete EHR and was only recently identified as the sole non-manual technical method to consume these test records, the majority of vendors have not done the work to implement the ability to consume QRDA 1. Therefore, most vendors will have to manually enter all data into the EHR.

   b) Based on competing priorities, the focus of vendors on being able to import the CCDA, and the fact that QRDA1 import is only needed for modular certification of the CQMs, it does not seem feasible to continue expecting EHRs to implement the ability to import a QRDA1. At the same

time, we recognize that manual data entry is excessively time consuming and some type of automated process would facilitate the data entry process.

RECOMMENDATION:

- *In addition to ONC continuing to support the option to use QRDA1 for importing the test data, we recommend that MITRE also incorporate the ability to use CCDA to generate that part of the patient data appropriate for automatic import, and provide the additional required data in user-friendly manual data files.*
- *In addition to the above, determine a more reasonable data set to use for manual entry, and continue to accommodate the option for sole manual data entry. (e.g., don't require the entry of 58 hysterectomies or 192 visits for one patient).*

2. The HTML patient data is not user friendly for manual entry.
   a) The HTML files do not contain enough information for some data elements for an EHR vendor to manually enter. Instead of naming the medication to be entered, we are given a generic drug category name and an RxNorm code. Since 99% of clinical users do not know RxNorm codes (or SNOMED or LOINC), many EHR systems do not provide a way to search for drugs by RxNorm code. Therefore, we have an additional step to go look up the RxNorm code using the https://vsac.nlm.nih.gov/ web site to find the right drug name. However, even the Value Sets don't have the actual names of the drugs needed.

      i) One vendor's example: patient 'GP_Peds A' has a medication entry of:

Medication, Active: Antibiotic Medications (Code List: 2.16.840.1.113883.3.464.1003.196.12.1001)	**RxNorm: 1013659**	April 30th, 2010 12:05 - April 30th, 2010 12:05	active

      ii) We looked up this medication by 'Antibiotic Medication' in the Value Set search and found "24 HR Minocycline 105 MG Extended Release Tablet".
      iii) When we added that drug name to our system, we found "Minocycline" but not at 105MG. We found that the drug name via Google for"24 HR Minocycline 105 MG Extended Release Tablet" is "Solodyn".
      iv) We were then able to enter "Solodyn" with the appropriate SIG into the system to get the appropriate RxNorm code into the database.
      v) If the HTML contained the right drug name, most of those extra steps could have been eliminated.

RECOMMENDATION:

- *Work with the vendor community to revise the test data set to eliminate issues like the above.*

3. The Cypress test patient records suffer from reported content errors that would lead to inaccurate test results, and, in some cases, would cause issues during the patient data load into the EHR. This situation is problematic, especially in light of the importance of data integrity, which was the topic of the Nov. 29th hearing on "Ensuring the Quality of Quality Data", and efforts by vendors to ensure there are checks and balances to prevent inaccurate data entry in their systems. There are multiple

examples and issues of such errors listed in the Project Cypress Talk Google Group, but here are a few of the most egregious:

a) Test record date ranges. The current test patient records have no encounters later than December 2010, with the result that none would qualify for the MU Stage 2 reporting periods. We were told in the ONC webinar on Certification of e-Quality Measures for Meaningful Use held on December 14, 2012 that test patient records will be updated to reflect date ranges within the Stage 2 reporting period. However, when we received the new test data in late December, the dates were not corrected.

b) Test data is not logically related or consistent. For example, there is a patient with an admission May 21, 1977-May 22, 1977. Associated with that admission are procedures performed in June, July, and August 1977, a diagnosis that became active on July 12, 1977 (two months after the admission) and was active for one day, and an intervention performed in September 1977.

c) Some test data elements start and end at the same instance, which is unlikely in actual practice and difficult for computation in some cases. (e.g., diagnosis starts and ends on exact same date/time).

d) Some data is not clinically realistic. Examples:

   i) Test patient who is discharged-deceased four times, none of which are the date of expiration.
   ii) The test patient has a diagnosis of “live newborn birth in hospital” at age 30.
   iii) The test patient has 58 hysterectomies.
   iv) Immunizations that last for eight hours.

e) Cypress includes data elements that are out of scope for the selected quality measures. EHRs are only required to support data capture of the elements required for the measures they are certifying on, so this is inappropriate.

f) The Cypress team currently has acknowledged several errors and incorrect warnings generated by their software:

   i) Requiring an NPI for an authoring device such as software.
   ii) Requiring a type attribute on a code element.
   iii) Mandating an optional code element.
   iv) Deviating from QRDA-I specifications where the Cypress developers think QRDA-I is in error.
   v) Requiring a birthplace state when optional birthplace is not populated.
   vi) Requiring optional attributes
   vii) Referencing a nonexistent conformance statement.
   viii) Incorrectly requiring gestational age entry.
   ix) Required payer data not included in the HTML data sets.
   x) Required clinical trials data not including in the HTML data sets.
   xi) Usage of incorrect and/or outdated value sets.

RECOMMENDATION:

- *Correct these and other identified errors in a priority order established in collaboration with the EHR vendor developers and other subject matter experts.*

4. For Eligible Hospital (EH) measures that include look-backs for previous hospitalization, Cypress assumes that the previous hospitalizations all occurred at the reporting facility. Under that model, Cypress produces a separate QRDA file for each previous hospitalization, going back many years - some of the test patients have upwards of 10 or more separate encounter files – and requires reference to these files in the measure calculation. This not only creates unnecessarily exponential numbers of patient records to be entered, it does not recognize the most likely scenario of hospitalizations at other provider facilities. In practice, to document according to the intent of the measure, providers record prior hospitalizations as part of the medical/surgical history of the current encounter.

   RECOMMENDATION:

   - *Allow EH test patient records to locate past hospitalization history as past admissions at the same facility or as part of the patient history.*

5. Test procedures using Cypress require that the EHR Technology database be cleared of all patient records prior to initiation of procedures. This requirement disregards the requirement that ONC Accredited Testing Laboratories ATL certification test procedures for all other functionality demands a robust database of test patient records. In practice, this means that certification testing would halt to clear a database for the sole purpose of CQM testing. Completion of pilot testing will demonstrate the impracticality and undue burden of these CQM test procedures in context with other functionality testing.

   RECOMMENDATION:

   We believe that there are several options to ensure the integrity of the test data, and have listed some suggestions below. However, we do not believe that any of this should be mandated by Cypress, but should be agreed upon by the certification body requirements.

   - *Run a baseline report before the certification test begins so that the ATL's can have a before and after look at patient data to determine if the system is calculating data accurately per the test. Allow for filters to parse out patients needed for Cypress testing from other patients in the database.*

6. Certification test procedures using Cypress have not been pilot tested with real electronic health record systems. Though such pilot testing is planned, it is expected that adaptation of test procedures will be required following such pilot testing. In the meantime, vendors are experiencing the time pressure of meeting implementation timeframes for their customers.

   RECOMMENDATION:

   See overarching recommendations at the beginning of this document.

7. Certification testing for CQM reporting of both Eligible Provider (EP) and EH measures was scheduled to open on January 2, 2013. The Cypress application continues to be developed and will not include full functionality for EH testing until April 2013. Consequently, CQM reporting

applications certified prior to April will be tested under different conditions to those tested after April.

a) In addition, we are not sure at this point when certification for CQMs will be generally available. In the meantime, we have customers who would like to have certified 2014 software available as soon as possible.

RECOMMENDATION:
We need clarification and a general understanding from ONC on how this will be handled.

8. On December 21, 2012, revised CQM specifications were published. These revised CQM specifications did not address all of the issues that had been identified by developers and others and, in addition, EHR vendors have reported logic and value errors in these revised specifications. ONC and CMS have advised that additional revisions will be published in April (EH) and June (EP).
   a) Please verify whether vendors who passed certification prior to release of revision, and then implement the revised specifications in order to provide correct measures to our customers, have any change to their certification status.

RECOMMENDATION:
Need ONC response to this issue.

9. During the January 10, 2013 demonstration, a question was asked as to how Cypress would be updated when new or revised measure specifications are released. The answer provided was that Cypress will not require updates when new specifications are released. We are unclear what this answer means and why Cypress will not require updates as measures are revised or added.

RECOMMENDATION:
We ask for additional clarification on the response to this issue, as we are unclear on the reason that Cypress and the test data sets would not need to be updated.

Request from EHR Association for testing of Cypress software prior to release of v2.2 – April, 2013

Email sent from Ginny Meadows, Quality Measurement Workgroup Chair, to Lauren Richie, Kevin Larsen, Carol Bean, Jacob Reider, Judy Murphy, Steve Posnack, and Deborah Krauss on April 17, 2013:

Members of the EHR Association Quality Measurement Workgroup have identified additional errors and issues with the latest 2. 1 version of Cypress that affect both the Cypress CQM testing software and the testing data produced by Cypress. We understand that a new version of Cypress, v2.2, will be released shortly. Therefore, the EHR Association Executive Committee has asked the workgroup to provide communication to ONC on this topic.

The Quality Measurement workgroup members respectfully request that ONC exercise its authority to require that the MITRE Corporation perform complete testing, including pilot testing, of the Cypress Clinical Quality Measure certification testing tool prior to the release of the 2.2 version, and subsequently, to all version releases. The workgroup will assist ONC and MITRE in this effort by assisting in the identification of member organizations that may volunteer to serve as pilot test sites. We also ask for clarification from ONC on the intended process to correct Cypress v2.1, and to perform testing prior to release of any updates to that version.

Cypress is described as the "gold standard" certification testing tool for Meaningful Use Clinical Quality Measure reporting, and is the standard of accuracy against which all electronic health record systems undergoing certification testing are compared. This key role demands that Cypress must undergo thorough testing to assure its accuracy. Every Cypress version release to date has contained significant errors that should have been discovered in thorough testing and validation processes, including pilot testing. The continued release of flawed test tools and test data has resulted in significant delays in achievement of 2014 edition EHR certification and unnecessary burden to the healthcare information technology community as we identify and report these issues and wait for them to be corrected.

For background, ONC certification testing of electronic health record technology using Cypress opened 1/1/13. Release levels have included versions 2.0, 2.0.1, and 2.1. As EHR vendors and Accreditation Test Labs have scheduled and initiated certification testing, significant issues have been discovered. EHRA members have provided constructive feedback to ONC and CMS regarding these issues both by email correspondence, in-person meetings, and the new JIRA issues tracking system. Since the JIRA system opened for us to use to track Cypress issues, 48 issues have been logged.

The EHRA provided formal written feedback on January 22, 2013 regarding, among other topics, the need to employ a thorough quality assurance, validation process to ensure Cypress readiness as a test tool for use with a large number of EHR technologies. Subsequently, Cypress 2.1 was released on 2/28/13 with no pilot testing, and vendors have identified issues that should have been identified in any testing process.

A new version of Cypress, version 2.2, is scheduled for release on 4/26/13 as we understand it. This version is anticipated to include revised measure specifications as well as correction of previous software bugs. We ask for clarification of the quality assurance process that will be used to ensure this

new version has been thoroughly tested. The EHRA Association feels that it is imperative to ensure that Cypress version 2.2 (and any future versions) are thoroughly tested, including pilot testing, and flaws corrected to the degree of accuracy expected of "gold standard" testing tools, prior to general availability for certification testing.

As experts on the development, quality assurance and implementation of software in the commercial market, the EHR Association members would be willing to advise on industry-standard testing procedures, and will work with ONC to identify members that may be willing to support the pilot testing of Cypress.

Respectfully,

Ginny Meadows, Chair, Quality Measurement Workgroup: Executive Committee, EHR Association
Jason Colquitt, Co-Chair, Quality Measurement Workgroup: Executive Committee, EHR Association

Response to ONC re: June Meeting – July, 2013

July 9, 2013

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Dr. Mostashari,

Thank you for the opportunity to meet with you and your team on June 17. Your engagement and candor were evident and much appreciated. This letter is in follow-up to that meeting.

First, we appreciated the opportunity to discuss improvements to the certification process. As your team requested prior to the meeting, the Association has identified a number of areas for potential improvement, some of which could lower costs for ONC, EHR developers, and providers. We were pleased that we were able to touch on some of these at a high level during the meeting, and we are pleased to attach our additional detailed recommendations to this letter. We look forward to further engagement on this topic, hopefully in the near future.

Our discussion concerning possible ways to "'Lean' out the certification process" was encouraging, and we are eager to follow-up on that topic separately. Some of our companies have extensive experience with Lean and similar methods, and we might be able to provide relevant resources and experience.

We also thank you for your candid explanation of the proposed vendor user fee for health IT certification, as well as your understanding of the Association's firm opposition to such a fee. We reiterate here our offer to support adequate ONC funding through appropriations.

We found the discussion of outstanding issues from our February 15, 2013, letter regarding Cypress and clinical quality measures (CQMs) issues very useful. We encourage you to continue to follow-up with Ginny Meadows and members of our Quality Measures Workgroup, as well as other vendor staff engaged in quality measures. We understand that we will be receiving a formal letter regarding Cypress and CQM issues soon. All of these discussions reinforced the need for a "single source of truth" within and across ONC and CMS on official meaningful use and certification materials, as we have discussed with your team for some time now.

We were also pleased to be able to continue the discussion on patient safety. As mentioned during the meeting, we are very grateful for ONC's input and support of the EHR Developer Code of Conduct, and your personal participation in our recent launch event made a real difference. We would be delighted to take Jodi up on her offer to explore the practical issues around reporting to PSOs, including the need to clarify the protections available to providers and vendors, and we hope we can hold those conversations soon given that we would like to see the remaining concerns addressed sooner than later.

Finally, we underscore the points made about the importance of allowing enough time between the start of Stage 2 and Stage 3, as well as the need for ONC and CMS to leave sufficient time between the issuance of all final regulations and guidance for Stage 3 and its start. The comments on the Health IT Policy Committee's Stage 3 Request for Comments submitted by the Association provide further detail on and rationale for our position. We are encouraged by signs emerging from HHS that Stage 3 is highly unlikely to start in 2016 and, as mentioned, request that such a shift be clearly communicated to providers and vendors as soon as possible.

Thank you again for meeting with us. We look forward to our continued work with you and your colleagues.

Sincerely,

/s/

Michele McGlynn
Chair, EHR Association
Siemens

/s/

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

/s/

Lauren Fifield
Practice Fusion, Inc.

/s/

Dr. Hatem (Tim) Abou-Sayed
Modernizing Medicine

/s/

Sam Holliday
Greenway Medical Technologies

/s/

Meg Marshall
Cerner Corporation

/s/

Ginny Meadows
McKesson Corporation

/s/

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 http://www.himssehra.org.

CC:
David Muntz, Principal Deputy National Coordinator
Judy Murphy, Deputy National Coordinator for Programs and Policy
Jodi Daniel, Director, Office of Policy and Planning
Jacob Reider, MD, Chief Medical Officer
Nora Super, Director of Public Affairs
Steve Posnack, Director, Federal Policy Division

Attachment 1: EHR Association Proposed Improvements in the ONC Certification Process (June 16, 2013)

Simplification

1. **Simplify the certification program**. Start from the top and evaluate each step/process. Some target areas could include:
   - Use JIRA to track certification issues broadly
   - Streamline the number of FACA workgroups and their various inputs
   - Reduce the prescriptiveness of requirements
   - Review deliverables, educational webinars, tip sheets, etc. - simplify and reduce in number (get as close to one source of truth as possible)
   - Evaluate the FAQ process

2. **Engage volunteer experts.** Include vendor experts much earlier on in the certification process in a formal way to help create high quality and workable deliverables from the start. In addition, help vendor experts understand the most effective way to provide feedback and acknowledge comments and questions submitted in feedback.

3. **Limited scope.** The scope of certification should be more targeted, with many fewer criteria. Reducing the number of criteria is an effective way to minimize the burden and expense of the certification process.

Timing and Readiness of Critical Materials

1. **Less frequent meaningful use and certification updates.** Certification should occur less frequently than every two-three years, with fewer restrictions around vendor software updates.

2. **Implement appropriate timelines.** Timelines for the program should be constructed in a way that permits ONC and its contractors to complete necessary work with sufficient quality prior to deadlines. In particular, testing tools, methods, and data should meet high quality standards before release. When issues are found, they should be promptly resolved (within weeks, not months).

3. **Use tested materials and mature standards.** Do not use or reference anything (e.g., standards, specifications, test tools) until they have been fully tested and reflect mature standards.
   - Do not incorporate CQMs into the certification process until they are tested and error-free.
   - Provide better quality control on data issues, with no obvious errors.
     - For example, there are RxNorm codes that were out of date and/or not being supported by First Data Bank, a broadly used formulary vendor.
     - There should be no obvious errors, such as nonsensical data or inaccurate codes. Such problems should be caught prior to release and the announcement that certification testing is available.
   - When there are issues, they should be tracked publically so that all EHR developers, Authorized Testing Labs (ATLs), and Authorized Certification Bodies (ACBs) can follow what has been reported.

- Data problems have slowed down the certification process for EHR developers, but we have generally found that ACBs have been good about making changes and/or escalating issues to NIST or ONC.

4. **Allow sufficient time.** Have the complete final set of information (e.g., rules, specifications, test scripts, CQMs), at a high quality level, available at least 18 months before the start of an applicable meaningful use reporting period.
   - We and our clients simply need more time to do things right and in a way that aligns with other customer priorities.
   - Indeed, it would be good if certification testing could be available 18 months prior to when that version of certified software will be in use.
   - The date certification testing will be available should be announced six months in advance.

Single Source of Truth

1. **There should be a single source of truth.** All certification-relevant materials should be available on one web site, with fewer types of documents that require versioning and notification of changes. All participants in the certification process would benefit from:
   - Clearer communication about standards changes that can affect certification, such as the recent QRDA changes by HL7 that were published as an erratum to the version cited in the regulations;
   - Better management of information on value sets (e.g., some value sets were missing from downloadable components from value set authority center);
   - Regular and timely notification of changes to test methods to minimize the confusion around version control for users.

Testing

1. **Measurement and testing should not drive product design and engineering. Avoid requiring EHR product engineering solely to meet testing and/or measurement requirements. The scope of this issue includes general testing, CQMs, and Automated Measure Testing.**
   - For example, the CQM certification requires additional development efforts that do not align with the standards specifications and meaningful use requirements. Also, Cypress requires the creation of QRDA-I transmission records using only one document per patient per measure, rather than the accepted method of transmitting one document per patient with multiple measures included.
   - Members have had to make engineering changes within the EHR in order to allow the entry of patient test data, in order to bypass the standard data entry edits in place.

2. **Testing should be streamlined.**
   - Use less complex and prescriptive requirements; working with the current requirements is very difficult and time-consuming.
   - Criteria should be written so that less than 15 minutes is required to demonstrate each one during certification. Faster turnaround is also needed in the testing process. One Association member reported that testing three modules took five hours.
   - Eliminate where possible any observed data entry for measurement in favor of prebuilt records and automated import capabilities for test data sets.

- If observed data entry is deemed necessary, allow testing in a manner that provides flexibility to vendors. The use of the QRDA specification to import data into an EHR that does not otherwise need to support import of CQM data is not feasible and is wasted development.
- Where attempts to automate testing introduce otherwise unnecessary constraints, such methods should be optional and manual testing methods should be permitted (e.g., the Cypress constraint on CQMs per XML file).

3. **Duplicate testing.** When a product is integrated and the testing requirement is the same for both eligible providers (EPs) and Eligible Hospitals (EHs), and common components are used for both domains, do not require the vendor to repeatedly test the same component for the same criteria requirement.
   - Currently, if the vendor presents the same component for the same criteria, whether in isolation for one criterion and then in combination with other EHR capabilities that cover other criteria but still is the basis for the same criteria as when tested in isolation, the vendor must test it again as if it never has been presented before.
     - For example, we may test the same capability to support e-prescribing or for a patient to view/download or transmit their data as its own EHR module and also in combination with other products or capabilities of ours that support other criteria. The fact our capability for eRX or V/D/T may be tested in isolation or in combination does not change the nature of it from a testing perspective.
   - We should either be able to credit testing done once toward meeting other criteria, or to modify the testing process so it is not a full repeat of what we have already done.

4. **Adaptation.** Make the "adaptation" claim process usable for technology porting. At present, such a claim would not result in a separate listing as would an "inheritance" claim for a version update.

5. **Certified Health IT Product List (CHPL).** Testing disclosure expectations should be clear and certification information on the CHPL should be more user-friendly.
   - Test methods should indicate clearly what information from a test will be made public with the EHR's certification (reports, test tool results, pass/fail).
   - The CHPL should be intuitive for provider users, reflecting good user-centered design principles.

6. **Specialty solutions.** Ensure that test data are relevant to specialty solutions that are likely to apply for modular certification, such as those focusing on obstetrics.

EHR Association QRDA Letter – November, 2013

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

[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. "

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."*
>
> *"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."***

[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.

> *"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.

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

[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.

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,

/s/

Michele McGlynn
Chair, EHR Association
Siemens

/s/

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

/s/

Lauren Fifield
Practice Fusion, Inc.

/s/

Dr. Hatem (Tim) Abou-Sayed
Modernizing Medicine

/s/

Sam Holliday
Greenway Medical Technologies

/s/

Meg Marshall
Cerner Corporation

/s/

Ginny Meadows
McKesson Corporation

/s/

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.

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