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July 31, 2012

Farzad Mostashari, MD, ScM
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200 Independence Avenue, SW
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Ms. Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Mr. Jeffrey Zients
Acting Director, Deputy Director for Management, Chief Performance Officer
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

(Transmitted Electronically)

Dear Dr. Mostashari, Ms. Tavenner, and Mr. Zients:

On behalf of the Electronic Record Association (EHR) Association, a coalition of 41 companies that develop, deploy, and support EHRs in thousands of hospitals and physicians' practices in the US, we would like to offer urgent, time-sensitive comments regarding the timelines associated with meaningful use Stage 2 final rules, test methods, and clinical quality measure specifications.

We are committed to the ongoing success of the meaningful use incentive program. Our members have invested significant effort reviewing and commenting on the proposed meaningful use Stage 2 requirements, and in preparing our software and our users for successful participation in Stage 2. In this regard, our Association provided detailed comments to both the Center for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC) on the proposed Stage 2 rules, including recommendations for additional steps needed in the CMS and ONC final rules to more completely address the challenges associated with the timing and start of Stage 2.

As August starts, we are extremely concerned, however, that the ability of current and future meaningful users to upgrade to and implement 2014 certified software by October

2013 for eligible hospitals (EHs) and January 2014 for eligible professionals (EPs) is jeopardized by a lack of necessary documentation and detail, most notably the final rules from CMS and ONC, clinical quality measure specifications, and draft or final certification test methods and scripts. This lack of information presents significant timing challenges that encompass development and testing of 2014 certified software, the certification process itself, the need for a large number of upgrades within very compressed time periods, and the time required for hospitals and physicians' practices of all sizes and varying complexity to modify workflows, test software, and train end-users.

In this letter, we summarize our observations and concerns based on our work with the Stage 2 proposed rules and our evaluation of the current timetable as we understand it, and provide specific recommendations, grounded in our regulatory comments, to mitigate as much as possible these timing-related challenges to program success.

As detailed in our public comments on the CMS and ONC proposed rules, we support and deeply appreciate the recognition that the original proposed Stage 2 timeline (beginning October 2012 and January 2013) did not allow for proper software development and implementation timelines, or the work required by our customers. Extending Stage 2 start dates for early meaningful users, and the start date for 2014 certified EHRs for all users, has been key to encouraging adoption and participation in the program. To ensure safe development and implementation, we have reiterated that a minimum of 18 months is needed between publication of final rules and associated documentation for a new meaningful use stage, and the first date that providers and hospitals must implement the certified software in order to maintain compliance with new requirements and thresholds.

We are concerned that, as final rules, clinical quality measures specifications, and certification test methods and scripts are not yet available – with final rules not expected until as late as September, and certification and quality measure documentation available later still – the timeline for vendors to develop software, perform appropriate quality assurance and user testing, obtain ONC-ACB certification, and deploy the software in provider organizations – and for providers to perform internal testing and end-user training, and determine any changes needed to procedures and clinical workflow – is much too short.

Even if the final rules are released in early August, development work would, for many areas of functionality, still be dependent on the additional detail provided in certification test methods (assuming that these are very close to the actual certification test scripts used by ONC-ACBs). Given the timeline for certification test script release in Stage 1, we are very concerned that release of test methods and scripts could take an additional four to eight weeks after the final rules are released.

We note that our work with the Stage 1 certification test methods and scripts was accelerated by the availability of draft test methods associated with the ONC interim final rule which were available prior to the final rules. As it appears that there will be no 2014 edition draft test methods, it is all the more urgent that test methods based on the final rules are available as close to simultaneously with the rules as possible. We want to be clear that, not having certification test methods and scripts until September or October leaves only a very scant 11 -12 months for the full cycle of final development, certification, and implementation of the software prior to the EH deadline of October 2013, and not much more time for EPs' EHRs.

Finally, we are concerned that this timeline does not allow for the inevitable corrections and refinements that occur after any final rules. For example, in Stage 1 an erroneous implementation guide was referenced in the ONC final rule and had to be corrected in further regulation, as well as numerous questions posed to both CMS and ONC that were addressed in subsequent multiple FAQs. Given the limited timeline, EHR developers will not be able to wait for corrections or answers prior to beginning their work, which means likely rework and extensive wasted effort when late guidance is issued.

As a further illustration of the need for both accelerated release of the final rule and mitigation of timeline-related issues, we note that ONC has estimated that EHR developers will spend 5,690 hours to develop new features and prepare products for certification. The EHR Association considers this estimate to be low as an average, and that it does not reflect the need for design that integrates new features into existing EHR workflows with careful programming and thorough testing. A more accurate estimate would be two-to-five times this ONC projection. A still conservative estimate of 10,000 hours of development would take a team of ten developers 25 weeks – with much of this work needing to occur after certification test methods are available (e.g., occurring from October 2012 through April 2013). Moreover, many EHR developers will need to add features to multiple products (for example, hospital and ambulatory modules as along with specialty modules, or multiple products used by different markets), or to multiple versions of a single product, in order to support existing users. EHR developers will struggle to develop and deploy thoughtful, usable, and safe enhancements in time for their users to implement prior to compliance deadlines. We note also that no estimates have been made regarding the time required by EHs and EPs to upgrade to or implement Stage 2 certified EHRs.

Given these concerns, and also mindful of the constraints facing CMS and ONC, we urge the following approaches to provide a more realistic timeline for both vendors and providers:

1. Expedite publication of the CMS and ONC final rules, certification test methods and scripts, and quality measures specifications. We emphasize that lags in availability of detailed test methods and quality measure specifications beyond the date of public availability for the final rules must be avoided as these detailed specifications are critical to our product development processes.

2. CMS and ONC should provide timely communication, as soon as possible, as to when this key information will be available to facilitate planning for EHR developers, eligible hospitals, and eligible professionals.

3. In making final decisions on the CMS and ONC final rules, align the scope of Stage 2 meaningful use and 2014 certification with what is feasible in the compressed timeline available for development and implementation.

4. Allow a 90-day reporting period for all providers during 2014.

5. Permit flexibility in 2014 for adoption of certified software and attestation by permitting use of 2011 certified software for those still reporting Stage 1 measures.

6. In addition, after publication of the rule, expedite any necessary corrections or clarifications to minimize wasted development, certification, and implementation effort.

In closing, we emphasize our commitment to the success of this program, and our keen interest in contributing to the successful transition from Stage 1 to Stage 2. We are anxious to begin this transition and urge that the final rules, test methods and scripts, and clinical quality measure specifications be published as quickly as possible so that we can continue to transition our users to more sophisticated meaningful use of their systems.

Sincerely,

Michele McGlynn
Chair, EHR Association
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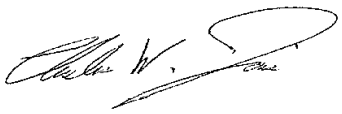

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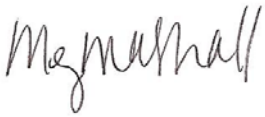

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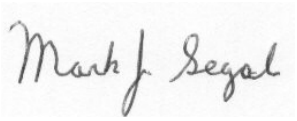

Mark Segal
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cc: Steve Lieber, HIMSS
John Daniels, HIMSS
Gail Arnett, HIMSS
Paul Tang, HIT Policy Committee

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.