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July 10, 2014

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Subject: Medicare and Medicaid Programs; Modifications, Revisions: Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; Health Information Technology (Docket ID - CMS-2014-0064-0002)

Dear Dr. DeSalvo and Ms. Tavenner:

Thank you for this opportunity to provide input on 2014 reporting options. Representing our nearly 40 member companies and our collective customers, we have attempted to respond rapidly so that CMS and ONC, in turn, are able to rapidly finalize 2014 reporting options. We emphasize the priority of a quickly issued final rule in eliminating wasted time and effort regarding 2014 work, and urge publication as soon as possible.

#### **Importance of Speedy and Clear Information**

We note that, due to time constraints, we anticipate that many physicians and hospitals will make decisions based on the proposed rule, as seems to have been your intent. We urge that these already-made decisions be considered as you finalize this rule, and that no changes be made in the final rule that would prove problematic for those who acted in good faith based on the proposed rule. We suggest some revisions in the following portions of this letter that we consider generally consistent with the proposed rule and not problematic for those physicians and hospitals that have embarked on a plan based on the proposed guidance.

**Clarify Text References “Due to Delays in 2014 CEHRT Availability” and Inability to “Fully Implement”**

In multiple places in the proposed rule, the text reads “[t]hese proposed alternatives are for providers that could not fully implement 2014 CEHRT to meet meaningful use for the duration of an EHR reporting period in 2014 due to delays in 2014 CEHRT availability” (emphasis added).

We understand from the preamble text in the NPRM, and also from CMS and ONC public presentations, that the intention of this proposal is to offer broad flexibility to providers challenged in meeting Stage 2 for many different reasons related to overall timing issues associated with Stage 2, including but not limited to:

- selecting an EHR that did not pursue EHR certification;
- using an EHR whose certification took longer than anticipated;
- needing to upgrade to an EHR system and having insufficient time;
- requiring additional time to implement new EHR features;
- lacking staff or resources to perform needed training to use 2014 certified functionality at a level sufficient to meet thresholds;
- the lack of readiness in the community for interoperable exchange;
- and/or lack of HIE or public health infrastructure.

Explicit clarification in the final rule that CMS understands that many scenarios could challenge a provider relative to Stage 2 timing, including but not limited to these, would be helpful, including confirmation that the flexibility offered is not limited to only the example scenarios given in the proposed rule. We similarly urge that this direction be given to CMS and state Medicaid auditors used for the EHR incentive program.

We note that this intended broad flexibility might be limited in practice by provider or other stakeholder interpretations of the phrase “delays in 2014 CEHRT availability.” Our first suggestion is to replace that phrase in the final rule with language that plainly states that the flexibility recognizes the multitude of timing-related challenges facing program participants, is intended to be broad, and that provider discretion is expected in applying this flexibility. An alternative or complementary approach would be to replace the language with a specific statement that more clearly encompasses the broad nature of the types of challenges presented, such as: “These proposed alternatives are for providers that experienced or experience Stage 2 timing challenges.”

We think that the most equitable approach to flexibility will permit participants to attest in 2014 for Stage 2 objectives, Stage 1 objectives as defined for 2014, or Stage 1 objectives as defined for 2013. Participants should be able to make their determination among these three choices for any timing-related reason.

We believe this simplicity, focused more generally on “timing-related challenges,” will better reflect the proposal’s intention as described in the preamble and by CMS and ONC staff in presentations on the proposed rule. It will also help avoid other unintended negative consequences:

1. This simplicity and clarity will avoid confusion and disputes over what constitutes a delay and what would be sufficient evidence of a delay for auditors. We already see significant time and effort invested in this determination, including requests for EHR developers to provide letters or other evidence that would guarantee a provider the ability to participate in this flexibility. Such confusion and disputes will not further EHR adoption or interoperability, and that time would be better spent preparing to hit Stage 2 thresholds in 2015.

2. This simplicity will help providers feel comfortable that they are not at risk by selecting to attest to Stage 1 requirements when they would otherwise be in Stage 2. Providers already feel significant risk of the possibility of an audit, and a complex flexibility provision will increase their uneasiness when it sounds that this is not intended. CMS has said in presentations that it is not intended to require extensive substantiation, and this change in language will help that to be understood.
3. This simplicity will minimize requests from EHR users to remove functionality associated with 2014 certification so that they can attest to availability delays. EHR developers have already received such requests, and effort put to this purpose would detract from the industry goal of advancing toward more sophisticated standards.
4. Finally, the simplicity will make these new options easier to understand, causing less need for education by regulators and EHR developers, and allowing more time to be focused on achieving Stage 2 goals in 2015.

#### **Options Proposed by the NPRM for Objectives**

We are concerned that the options proposed by the NPRM in Table 2 are complicated and overly restrictive.

We suggest, as proposed above, that CMS permit providers to attest in 2014 using any of the following four options for any reason at the provider's discretion, based on a documented timing-related concern, and using either 2011 or 2014 certified EHR technology:

1. Stage 2 objectives and measures
2. 2014 Stage 1 objectives and measures
3. 2013 Stage 1 objectives and measures
4. A combination of 1-3 that best matches with the needs of the attesting provider

The EHRs in use by providers will influence which of these choices best meets their needs. For example, if a provider has not yet upgraded his EHR to 2014 certified versions, he might find that option 3 best meets his needs. In another example, users of EHRs who have upgraded to 2014 certified versions might find that 2013 reporting options are no longer available to them. In addition, we note that, as EHR developers, given the expiration of 2011 certification and the conclusion of 2013 reporting, some EHRs no longer contain 2013 reporting features or have replaced 2013 reporting features with 2014 reporting features, so it may be infeasible in many cases for providers to not upgrade to the 2014 edition if they wish to attest in 2014. Working backwards to retrieve such features would generally be time intensive and not particularly valuable.

Fundamentally, we do not see an advantage to CMS programmatically limiting attestation options based on the certified EHRs in use. We think the best path will be if CMS permits a very flexible choice for attestation and EHR developers educate their users on which options are feasible.

We understand that there are concerns about updating CMS' attestation system to permit this flexibility. We are not certain that we understand the nature of these concerns. As software developers, it does not seem more complex to update a website with a wizard to guide a user through data entry in this manner than with the built-in restrictions proposed in the NPRM. We suggest that the user could first select which type of objectives he or she was going to enter (as listed above) and then be taken to the pages to enter those choices.

We are concerned that this perceived complexity of updating CMS' attestation portal will lead to an overly complicated flexibility option. The complexity of the NPRM's proposal, driven in part by concerns about portal capabilities, has several negative consequences that we see as avoided with a more flexible option:

1. The complexity confuses EHR users and requires additional effort from CMS, ONC, and EHR developers in education about what options are permitted and what is appropriate.
2. The complexity appears to, in effect, penalize early adopters by limiting their options to the more challenging 2014 attestation choices of hitting Stage 2 thresholds or the 2014 revised Stage 1 thresholds. Early adopters should never be penalized, with such counter-intuitive "penalties" driving an industry-wide reluctance to be first and move toward new standards and goals.

For example, consider a provider who was able to meet 2013 Stage 1 thresholds for electronic access to the EHR, but has not been able to meet the 2014 Stage 1 threshold for electronic to the EHR. In the proposal, if this provider has already upgraded to 2014 certified software, he must meet the 2014 threshold or not be able to participate as a meaningful user. If he has not upgraded to 2014 certified software, he could participate as a meaningful user with the lower threshold. It does not seem that early adopters who have made significant progress toward industry goals by upgrading to software certified against the most recent criteria should be penalized by having to reach a higher threshold than those who are less prepared. So, we believe that a provider with the 2014 CEHRT implemented should also be able to meet, as feasible, the 2013 Stage 1 objectives and measures based on a timing concern as discussed above.

#### **Options Proposed by the NPRM for CQMs**

We are also concerned that the options proposed by the NPRM on pages 29736-7 are complicated and overly restrictive.

The proposal does not account for the fact that the EHR modules in use for (g)(1) or (g)(2) automated measure calculation might be completely separate and upgraded on different schedules than the modules in use for (c)(1)-(3) clinical quality measures. The proposal also does not accommodate the scenario where a provider has upgraded his CQM module to 2014 criteria already, but has not yet upgraded his module used for reporting objectives.

We suggest that CMS delink which CQMs are attested to, from which objectives are attested to. We suggest permitting providers to attest to either of the following clinical quality measure options in 2014 for any reason at the provider's discretion, regardless of what meaningful use objectives and measures choice is selected, so long as the CQMs are supported by the CEHRT to be used for reporting:

1. 2011 CQMs
2. 2014 CQMs

#### **Looking Ahead to Stage 3**

We appreciate the proposal to confirm, in regulation, the schedule for the onset of Stage 3, as was described in the December 2013 press release. This advance notice of the schedule for upcoming years is important for EHR development and hospital and provider implementation planning, both of which plan several years in advance.

We are concerned, however, that the proposal for the Stage 3 timeline presents many of the same challenges as were encountered in Stage 2. For example, the EHRA has consistently given feedback that 18 months, after all of the guidance (rules, specifications, test procedures, test tools, test data, implementation guides, etc.) is final and available, are required for safe development and distribution of new features. These targets were not achieved in Stage 2 timelines and contributed to the challenges intended to be alleviated by this flexibility proposal. Unfortunately, when we examine the proposed timeline for Stage 3, we see a similar lack of sufficient time. By our estimates (see table below), there will be less than 12 months between the expected publication of final certification test procedures corresponding to Stage 3 and the beginning of hospital reporting periods for FY 2017 in October 2016.

	<b>Stage 2 Schedule</b>	Months to beginning of reporting periods	<b>2017 Stage 3 Proposal</b>	Months to beginning of reporting periods	<b>2018 Stage 3 Proposal</b>	Months to beginning of reporting periods
Final Rule	August 2012	14 months	? July 2015	15 months	? July 2015	27 months
Final certification test procedures published	November 2012	11 months	? October 2015	12 months	? October 2015	24 months
CQM specifications published	December 2012	10 months	?		?	
Beginning of reporting periods	October 2013	NA	October 2016	NA	October 2017	NA

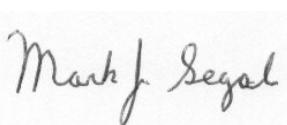
We suggest that careful review of this timeline is needed. **Given the current situation of the industry, we suggest finalizing Stage 3 as beginning no earlier than 2018.** This revised timing will permit more time for regulatory work as well as the EHR development and implementation that will be needed for a successful conclusion of the program. If Stage 3 begins in 2017, a significantly smaller scope than in Stages 1-2 is needed to be even potentially feasible in the proposed timeframe, but still with likely risks associated with compressed timing.

Moreover, the timeline for the future of the Meaningful Use EHR Incentive Program must enable the HIT Policy Committee, CMS, and ONC to learn from the experience in one stage and have that inform the next stage. We realize that the flexibility offered in 2014 might have the negative consequence of enabling collection of less data on Stage 2 progress and achievement and therefore provide less data to inform decisions about Stage 3. We would not like to see this consequence, and would suggest that CMS consider collecting additional information from providers attesting to inform these future decisions.

Important areas for data collection would be: patient engagement with secure messaging, patient engagement with viewing, downloading, and transmitting their records, and industry progress with interoperability at transitions in care. We are concerned that if the only data CMS has when setting Stage 3 objectives is from those who have been successful with Stage 2, the challenges of some of the thresholds will not be fully understood. Some providers will be willing to volunteer additional data on their progress on Stage 2 measures to inform Stage 3, and we see this as advantageous to the long term success of the program.

On balance, considering these factors, we urge that any timeline changes, whether they are to the date Stage 3 starts or to the reporting periods for any future year (such as shortened reporting periods in 2015, 2017, or 2018) be made public as soon as possible so that the information can be used for advanced planning. Being able to rely on clear and consistent signals will be key to future success with this program.

Sincerely,

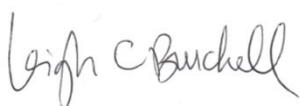


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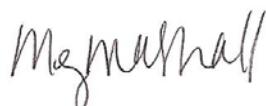
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**About HIMSS EHR Association**

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 HIMSS. For more information, visit [www.ehrassociation.org](http://www.ehrassociation.org).