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April 1, 2016

Alicia Morton DNP, RN-BC
Director, Health IT Certification Program
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services

Dear Captain Morton,

The Electronic Health Record Association wishes to bring to your attention a serious usability issue uncovered in how the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare and Medicaid Services' (CMS') reporting expectations for the EHR Incentive Program for Stage 3 in the 2015 Edition test procedure[1] and test data[2] for (g)(2) automated measure calculation. This interpretation may have inadvertently increased the ONC certification rule's scope and further implied an implementation approach that is not conducive to accuracy of measurement or program efficiency.

Our Meaningful Use Workgroup has carefully reviewed the issue and finds that, for certain measures (e.g., Objective 6: Patient Education/Required Test 3), the test data requires the EHR to demonstrate that, after attestation is completed, further education provided to a patient (or other analogous actions for different measures) no longer increments the numerator. The affected portions of the (g)(2) criterion seem to be:

- Required test 3
- Required test 4
- Required test 5
- Required test 7
- Required test 8

We are concerned that, without revision, this test data will be interpreted literally and will require vendors to have prescriptive solutions that require providers to enter an attestation date in their EHRs. Our provider customers have told us that this additional data element provides no clinical value, and further, our experience tells us

[1] https://www.healthit.gov/sites/default/files/170_315g2_automated_measure_calculation_v1_0.pdf (as of 3/19/2016)
[2] https://www.healthit.gov/sites/default/files/170_315g1g2_2015_test_data_v10.xlsx (as of 3/19/2016)

that the information will be entered sporadically or incorrectly, thus causing program inefficiency and wasted provider resources.

We are also concerned that the prescriptive implication of the test data may limit the ability of EHR developers to develop other innovative solutions to mitigate the usability impact of the 2015 certification requirements. Finally, we are worried because this requirement has emerged in the certification test procedures and test data, which are not widely reviewed by the provider community and, as such, the provider community may not escalate the issue directly.

To further elaborate on the issue, consider Objective 6, test 3 as an example. The test data requires the EHR to demonstrate that, "after attestation is completed", further education provided to a patient no longer increments the numerator. This result cannot be accomplished by limiting the increments to the numerator to education provided during the reporting period (an approach common with other measures) because education provided up until the date of attestation is evaluated and expected to increment the numerator. In conversations with ONC staff, Association members have also learned that this requirement is not intended to be accomplished by restricting providers to education provided up until the standard end of the attestation period (i.e., the end of February of the year after the reporting year) because this restriction would not account for some scenarios such as:

- Providers in their first year with a 90-day reporting period;
- CMS making a last-minute extension of the attestation deadline into March;
- State Medicaid programs selecting alternate attestation deadlines which might be later after the calendar year.

Therefore, it seems that this certification requirement requires the ability to document the date of attestation for each participating eligible provider (EP) and eligible hospital (EH), and to then use that date in the calculation.

Some EHR Association member companies already have features in their software to record date of attestation, and they reported during our discussion that this data element is rarely, if ever, populated by users. When it is populated, there is some concern about accuracy, as users do not always update the date even if they rerun reports and potentially make a change in the CMS web portal. Also, our members have seen situations where the date is populated for a group of practitioners as all being the same date, when it is more likely that the actual attestation dates for the group ranged over several days of data entry to the CMS web portal.[3] Other member companies report not receiving requests for this ability from their users at all, and have therefore not added it.

In total, this experience leads EHR developers to the conclusion that this documentation has little value to clinicians. It also leads to the conclusion that if this certification test step is not modified or clarified in a way that allows appropriate feature development, documenting the date of attestation in the EHR (and not as part of other materials preserved after attestation) would be a net new documentation expectation for most participants in the meaningful use program, and one which experience has shown is not effective nor efficient. We are unclear as to why this was added since by definition, the attestation will have been done so there would be no need to evaluate numerators for that reporting year.

Because this is a requirement of certification and not of meaningful use, it is possible that the expectation is that the tool be available to providers but not necessarily used. However, we are concerned that the requirement to make the tool available in this specific way will lead meaningful use

[3] Across several thousand EHR users with this capability, the data element was found to be populated less than 5% of the time, and when it was populated the data was sometimes an estimate (not the precise date of attestation).

auditors to expect that reports consistently cease incrementing after the date of attestation; and that if a provider fails to document their date of attestation in the EHR and then subsequently determines a need to rerun a report, this would leave him or her at risk during an audit. The combination of the certification expectation and audit risk mitigation will lead providers to consider this documentation essential, even if they see it as having little or no value.

In our experience, providers do not routinely familiarize themselves with the ONC (g)(2) test data to the point that they will realize this as a net new documentation expectation. We are concerned that providers generally expect new documentation requirements to have been expressed in the CMS proposed rule and made available for public comment in that process. The Stage 3 proposed rule and final rule do not appear to have requested feedback from providers on this documentation requirement nor alerted them to the upcoming change.

Discussion among the Association's Meaningful Use Workgroup members has determined that, in the past, different EHR developers have taken different approaches to how they provide tools or assist users in running reports and preserving necessary materials for audits. These approaches have been developed by each company working with its users to understand their needs and design workflows to address those needs.

Across many different EHR products, some approaches include (but are not limited to):

- Methods to include activities post-reporting period and prior to attestation and then
    - preserve attested-to-reports within the EHR for audit purposes
    - export reports for preservation outside the EHR
- User-configurable date ranges for the period in which what data is counted by the EHR
- Limits to incrementing numerators at the conclusion of the expected CMS attestation window (the end of February following the reporting year)
- Mechanisms to default when reports are no longer run or incremented, but to request additional reports after that point
- Saving a backup of the database from the date of attestation, to be restored in the event of an audit

We are concerned that the prescriptive nature of the ONC 2015 Edition test procedure and test data for (g)(2) automated measure calculation will not permit the diversity of approaches that developers have previously worked out with users regarding reporting and archiving of attestation reports, nor does it allow for development of innovative future approaches.

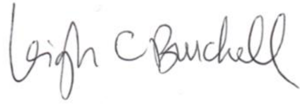
Therefore, we strongly encourage modification of the ONC 2015 Edition test procedure and test data for (g)(2) automated measure calculation. We suggest that the test procedure be revised to indicate what we understand to be the intent of the requirement, which is that the EHR support the user in retaining a copy of the automated measure calculations that he or she uses in attestation. With a less prescriptive requirement, this intent could be met:

- Without requiring net new documentation that clinicians see as having little value;
- Using a variety of tools designed in conjunction with EHR users; and
- Using yet-to-be designed innovative tools that are designed in conjunction with EHR users.

We understand that CMS and ONC both share the EHR Association's concern that the meaningful use program not reduce EHR usability or overly burden provider participants. We are hopeful that

addressing this issue with the (g)(2) certification test will align with that shared goal, and contribute to the ongoing success of the meaningful use program.

Sincerely,



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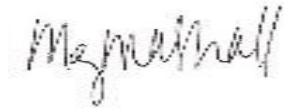

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

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