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June 15, 2015

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-3311-P
Baltimore, MD 21244-8013

**Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program -
Modifications to Meaningful Use in 2015 Through 2017**

Dear Administrator Slavitt,

The Electronic Health Records Association (EHRA) appreciates this opportunity to comment on the proposed “Modifications to Meaningful Use in 2015 through 2017” rules. As developers of electronic health record (EHR) systems, we have extensive experience with developing products for certification by the Office of the National Coordinator for Health IT (ONC) and assisting EHR users in participating in the meaningful use (MU) Stage 1 and Stage 2 programs, which informs our attached suggestions.

Established in 2004, EHRA is comprised of almost 40 companies that supply the vast majority of operational EHRs to ambulatory practices and hospitals across the United States, in addition to other forms of health IT designed to support the nation’s delivery system reform initiatives. The EHR Association operates on the premise that the rapid, widespread adoption of health IT 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 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 efforts to simplify and focus meaningful use in this modification proposal will be key to the ongoing success of the EHR Incentive program. Given the limited time available left in 2015, we urge that a final rule is issued as quickly as possible in order to maximize its positive impacts on the program for 2015 and 2016.

In the attached detailed comments, we have noted areas where we think appropriate simplicity will aid the program, such as in the single definition of MU and unified

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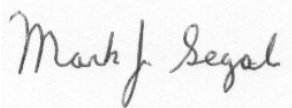
June 15, 2015

reporting periods. We have also noted areas where past experience with MU leads us to believe there will be complexity and inefficiency, and we offer alternative approaches where feasible.

Finally, EHRA appreciates CMS' clarity that the proposed changes to MU in 2015-2017 will continue to leverage investments made by EHR developers and providers in ONC 2014 Edition certified EHR technology (CEHRT), and that changes to software are not expected.

Thank you for your consideration of our suggestions. EHRA is available to provide any assistance that we can to you and your staff on these and other issues.

Sincerely,

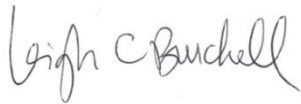


Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

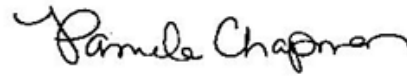


Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



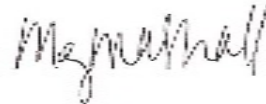
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association

and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

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

EHR Association

Detailed Comments on

Modifications to Meaningful Use in 2015 Through 2017

Single Definition of Meaningful Use

We agree with CMS' assessment that a single definition of meaningful use (MU) applicable to all program participants, regardless of when they first began to participate (with the proposed flexibility for Stage 1 providers in 2015), will provide helpful simplicity to the program that will benefit EHR developers and EHR users. We are strongly committed to achieving success in the area of interoperability, and we agree that having all participants on the same standards and timelines will better facilitate meeting interoperability goals.

Aligned EH Reporting Period with Calendar Year

We support overall CMS quality measurement alignment to reduce the burden on providers. In this regard, we agree that it makes sense to align the meaningful use eligible hospital (EH) reporting periods with the calendar year as proposed, which would also match the hospital IQR quality measurement reporting periods. We do ask that CMS be mindful of potential disruptions for hospitals in 2015 relative to anticipated MU incentive payment timing.

2014 Edition CEHRT

Use of 2014 Edition in 2015-2017

EHRA appreciates CMS' clarity that the proposed changes to MU in 2015-2017 will continue to leverage investments made by EHR developers and providers in ONC 2014 Edition certified EHR technology (CEHRT), and that changes to software are not required for providers to be successful. When software changes and updated certification criteria are needed, sufficient time for development, testing, and implementation must be allowed, and such time is not available for reporting years that are already half over. We strongly urge that any proposed changes considered in the final rule be evaluated to determine whether they are feasible with ONC 2014 Edition CEHRT, and that achievability with ONC 2014 Edition CEHRT be a key principle for determining what changes can be made mid-course in 2015 via this rule.

Automated Measure Calculation of Topped Out Measures

To reduce market barriers for new EHR products, we suggest that, once the final rule making these changes takes effect, new EHRs presented for certification no longer be expected to certify to the automated measure calculations (ONC's (g)(1) and (g)(2) criteria) related to measures that have been determined to be "topped out." Certification testing for automated numerator calculation and automated measure calculation is time consuming and expensive, so requiring this for all new EHR products when the measures are no longer necessary for program participants would be an unnecessary expensive barrier for new entrants to the marketplace.

Reducing Complexity

We appreciate CMS' goal of reducing the overall complexity and burden of the MU program. We agree that the objectives that CMS has proposed be considered "topped out" have seen high levels of success across the industry and can be removed in favor of focus on higher priorities.

We have reviewed the CMS-published data on past achievement of meaningful use thresholds and observed that providing patient education materials has similarly seen high levels of achievement. We

recommend this objective also be considered “topped out.” The patient education objective has in the past been especially prescriptive and limiting to providers in the methods that they can use to select patient education for their patients. Given the limitations of attempting to measure this objective and the high rates of past meaningful users, we consider it a candidate to be topped out in favor of a narrower focus on other priorities.

Unintended Consequences

We have identified two portions of CMS’ proposed modifications that we are concerned will have the unintended consequences of making the program more complex and burdensome to providers, rather than less so. We explain the issues here and offer suggestions for resolution.

- **eRx**

The proposed rule suggests that in “modified Stage 2”, all hospitals would need to achieve in 2016 and beyond what was previously a Stage 2 menu objective -- discharge e-prescribing. The timeline between the expected finalization of this regulation and January 2016 is not sufficient for all hospitals to implement discharge e-prescribing, given that some hospitals were not planning this as part of their menu set. Discharge e-prescribing would be better introduced as required for EHs in Stage 3. That timeline would allow sufficient time for implementation.

- **Public Health**

CMS suggested several changes to the public health measures to align “modified Stage 2” with Stage 3. These proposals place obstacles in the way of providers wishing to meet MU in 2015-2017. We offer several suggestions below to mitigate burden on providers and align with the 2014 Edition CEHRT.

Proposed Panel of Options

EHRA requests clarification so that we understand the proposal correctly, and we suggest that the following are examples of how EPs and EHs could successfully meet the public health panel:

1. An EP submits to an immunization registry and submits to a public health registry.
2. An EH submits to an immunization registry, submits reportable labs to public health, and submits to a clinical data registry.
3. An EH submits to three clinical data registries.
4. An EP submits to an immunization registry and proves that she is excluded from syndromic surveillance reporting, case reporting, public health registry reporting, and clinical data registry reporting.

Active Engagement

We agree that “active engagement” is a more appropriate criterion than “ongoing submission”, given that not all engagement involves ongoing submission, and the fact that ongoing submission (while obviously the goal) is often dependent on factors outside of EP or EH control.

List of Registries

EHR developers and providers will find significant value in a list of registries that are able to accept data using the standards identified for certification. We strongly encourage the creation and central maintenance of such a list.

Standards

Several of the proposed public health choices seem to reference standards that are not part of ONC 2014 Edition CEHRT. For example, there is discussion of bidirectional immunization exchange (new in the 2015 Edition) as well as case reporting and public health registry reporting (new in the 2015 Edition).

In addition, the proposed clinical data registry reporting measure has no identified standards in any version of CEHRT.

We recommend that CMS clarify explicitly that either 2014 Edition or 2015 Edition (after it is finalized, available for certification, developed, and implemented) be permitted in 2015 to 2017, and that any implications or dependencies on 2015 Edition implied in the 2015 Modifications NPRM be excluded from the final rule.

Proposed Public Health Approach

To reduce the burden of the public health proposal, we suggest instead that CMS require the following:

- EPs must either demonstrate active engagement with an immunization registry or qualify for an exclusion.
- EHs must either demonstrate active engagement with or qualify for an exclusion from all three of the following: immunization registries, syndromic surveillance, and reportable lab results.

This proposal is simpler, avoids dependencies on new versions of CEHRT and avoids complexity where providers are excluded from immunizations and then required to prove that they are excluded from all other possibilities, an onerous task.

Exclusions

We anticipate that many registries and public health agencies will not be able to receive data using the standards specified in this timeframe. Therefore, we anticipate many EPs and EHs will be attempting to prove that they are excluded from the measures, and that proving an exclusion could generate a great deal of bureaucratic work without benefit to patients. We considered the following challenges:

- Certain exclusions are jurisdictionally-based, when specialty-based seems more applicable (e.g., clinical data registry reporting).
- It is not clear what a sufficient level of due diligence is for a provider to prove that there were not applicable recipients for submissions, causing concern for EPs that their documentation will be considered insufficient during an audit.
- Some registries impose their own requirements, which can include additional data capture requirements beyond what is in CEHRT, proprietary certification, licensing of their submission methods and content, membership in their organization, fees/dues, or transport mechanisms that are beyond what are standardized in certification.

We recommend that CMS amend the public health exclusions to address the challenges presented above, at least until a centralized list of registries is available.

8.1 Immunizations

EHRA observes that immunization registry reporting is the most widely adopted public health submission today, and that submission would be more efficient if public health agencies standardize to the same requirements that EHRs must meet in certification as well as a common transport mechanism. We urge HHS to work on standardization for registries to further the overall goal of national interoperability. In particular, we are concerned that the Centers for Disease Control (CDC) seem to be working on additional and conflicting EHR certification, which we do not believe will add value.

8.2 Syndromic Surveillance

Urgent Care

It is unclear why CMS has removed urgent care contexts from EP MU and included them in EH MU. Urgent care is not a place of service that would otherwise fit CMS' definition of EH, and urgent care providers successfully participate in the MU program as EPs. We suggest that CMS correct these references on syndromic surveillance to match the broader context of the EP/EH definitions.

EP Objective

There is no implementation guide for this standard, reflecting a lack of priority interest among receiving agencies across the country. Given this lack of interest and lack of standards, EHRA does not believe that this is an appropriate MU objective for EPs. We suggest that it be removed as an EP option. If an EP is able to submit to his or her jurisdiction, then this could be considered sufficient to meet measure 8.4.

8.3 Case Reporting

EHRA is not aware of any public health agencies accepting reportable condition case reports using the standards identified for certification. We question whether this measure is really practical for widespread adoption.

8.4 Public Health Registry

CMS seems to anticipate a broader range of public health registry submissions than are included in 2015 ONC certification. If preserved in 2015-2017 as an optional measure, CMS will want to clarify that use of specifically certified CEHRT is not expected, since there are not corresponding standards in the 2014 Edition. Likewise, the broadening of this category beyond cancer registries poses the same challenges as case reporting, since these new registries would have to be identified and fielded in a very short period of time. We suggest limiting the scope of this registry type at least through 2016 to allow for meaningful adoption.

8.5 CDR

There are no standards identified by ONC in 2015 or 2014 Edition CEHRT for submission to clinical data registries. Even if a standard were to be added, there is not an applicable standard to suggest and we are uncertain how a standard would be identified. There are currently many clinical data registries, but they do not use a single standard. Each registry has widely varying:

- expectations for what data is submitted;
- submission formats;
- submission transport mechanisms.

Submission to clinical data registries would be far more efficient if a single standard could be identified for the data submitted, how it ought to be formatted, and how it is transported. However, EHRA is under the impression that registries have such varying use cases for what they do with the data that they are not close to standardizing in that fashion.

CMS should clarify that clinical data registry submission does not need to use CEHRT to be considered sufficient for measure 8.5. Given that change, the exclusions will also need to be adjusted to account for submission not being feasible given the current data capture and registry requirements.

8.6 Reportable Labs

We do not have any specific comments on submission of reportable lab results beyond our general comments on all of the measures in this objective.