HiMSS Electronic Health Record Association

33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 312-915-9582
Email: agorden@himss.org
Twitter: @EHRAssociation

AllMeds, Inc.
Allscripts Healthcare Solutions
Amazing Charts
Aprima Medical Software, Inc.
Bizmatics
Cerner Corporation
CureMD Corporation
e-MDs
EndoSoft
Epic
Evident
Falcon Physician
Foothold Technology
GE Healthcare IT
Greenway Health
Healthland
MacPractice, Inc.
McKesson Corporation
MEDHOST
MEDITECH
Modernizing Medicine
NexTech Systems, Inc.
NextGen Healthcare
NTT DATA, Inc.
Office Practicum
Practice Fusion
QuadraMed Corporation
Sevocity, Division of
    Conceptual MindWorks Inc.
SRS Software, LLC
STI Computer Services
Vālant Medical Solutions, Inc.
Wellsoft Corporation

December 15, 2015

Andy Slavitt
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310 and 3311-FC
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Mr. Slavitt:

Representing more than 30 member companies of the Electronic Health Record Association (EHRA), we are pleased to submit the following comments on the final rule for Stage 3 of the meaningful use incentive program. These comments were developed through a collaborative effort of our workgroups that focus on meaningful use, certification, and public policy in order to provide the perspectives of health IT professionals who specialize in those areas.

In general, we are concerned that the proposed timelines will not be adequate if there are substantial changes in CMS programs that change meaningful use requirements (e.g., EHR Incentive Program, MIPS). EHR developers have already begun development work based on the recent CMS and ONC final rules, which may turn out to be wasted, incomplete, or insufficient effort if subsequent regulations or guidance make material changes to underlying needed functionality or measurement criteria for meaningful use.

More specifically, the EHRA is requesting clarification on a number of objectives and measures, as detailed in the attachment. We also recommend aligned numbering between the CMS meaningful use objectives and measures, which developers and their customers have found confusing in both Stages 2 and 3.

We look forward to continuing our ongoing productive dialog on this important program to ensure that our customers are able to adopt new features in a timely fashion in order to comply with its requirements.

Sincerely,

Leigh Burchell
Chair, EHR Association
Allscripts

Sarah Corley, MD
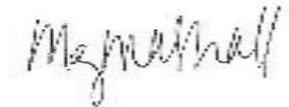Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion

Meg Marshall, JD
Cerner Corporation

Rick Reeves, RPh
Evident

Ginny Meadows, RN
McKesson Corporation

Sasha TerMaat
Epic

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.

EHR Association (EHRA) Comments on Meaningful Use Stage 3 Final Rule

Timelines

EHR developers have begun careful analysis, user-centered design, and development work to prepare for the aggressive timelines laid out for meaningful use Stage 3 (MU3). Given these investments, we are concerned that further changes introduced in other CMS programs will have potential impact on MU3 in ways that would interrupt the work of EHR developers and negatively affect the timelines and associated assumptions made by CMS in this final rule. For example, we are worried that if another final rule, changes in MIPS, or other regulations further modify what is expected in the future of meaningful use (whether for MIPS or more generally), work already invested in EHR features or certification would turn out to be wasted, incomplete, or insufficient. Future program changes must consider the investments already being made that are based on present regulations and guidance. In addition, the implementation timelines set out in the final rule will need to be revised if subsequent regulations or guidance make material changes to meaningful use that affect either underlying needed functionality or measurement.

Numbering

It is confusing to both providers and developers that CMS does not use a consistent numbering system for objectives and measures in this program. In particular, the inconsistency between the 2015 Stage 2 measures and those for Stage 3 is confusing. We, therefore, urge CMS to align the organization and numbering of objectives and measures across programs.

Objective 1 - Protect Patient Health Information

We do not have any comments.

Objective 2 - eRx

We are confused with the change of language regarding e-prescribing controlled substances and seemingly conflicting references as to what is expected. For example, on page 300, the discussion indicates that providers "must may" include controlled substances. Can CMS clarify this area?

Objective 3 - CDS

There are several elements in the Stage 3 final rule that are confusing, and we suggest clarification.

First, there seems to be a misunderstanding of common implementations of the Infobutton standard. Page 62836 describes how Infobutton referential linking is intended to be measured:

> *The InfoButton standard can be used to provide hyperlinks to information, such as clinical guidelines or patient data summaries, at the relevant point in the care continuum and therefore represents one type of CDS that EPs, eligible hospitals, and CAHs may use to meet the EHR Incentive Programs CDS requirements. There are also likely to be cases where it makes sense for a CDS resource to display certain attributes at the time of presentation, or for a resource to include an InfoButton linking to additional information with CDS attributes. The potential workflows and implementations of these resources within a CDS is varied and should be tailored to best meet the provider's needs. However, please note that in this example, the use of the InfoButton would not count as a separate or additional CDS intervention, but rather would be a supporting part of the one CDS of which it is a part.*

We are not sure what it means that *"use of Infobutton would not count as a separate or additional CDS intervention, but rather would be a supporting part of the one CDS of which it is a part."* Does this mean

More than Ten Years of Advocacy, Education & Outreach
2004 – 2015

December 15, 2015

that providers are required to implement Infobutton linking, but are not able to count it as one of their interventions?

This measurement description does not align with what we know to be common implementations of the standard, where referential linking is not enabled as part of one or more specific interventions, but is generally made available for entire categories of information. For example, a system would enable linking for all problems, or all medications, or all immunizations. When linking is enabled for multiple types of categories, it is not clear how that ties to any particular CDS interventions.

Second, CMS seems to limit what providers are able to use for CDS with this description on page 62837:

> *Response: CMS does not certify CDS functions or resources, but instead defines that a provider must use CDS resources and that those resources must meet the ONC certification criteria to meet the definition of CEHRT. The EHR Incentive Programs do not otherwise restrict a provider's ability to choose any CDS option or resource to meet their unique needs. For the certification criteria for CDS, the ONC 2015 Edition proposed rule (80 FR 16804 through 16921) proposed the functionalities that health IT developers would build into their ''CDS module'' to meet the certification criteria. These ''CDS modules'' are what meet the CEHRT definition for the EHR Incentive Programs. However, while the certification rule specifies that the ''CDS module'' that is certified to the CDS standard must have certain capabilities to provide or enable CDS for provider use, it does not certify the supports or resources themselves. This means that the ONC health IT certification criteria are designed to ensure that the ''CDS module'' implemented by EPs and eligible hospitals and CAHs will enable them to meet the CDS Objective requirements without limiting the potential use and innovation of a wide range of options for providers.*

Take the following example: a system has the ability to configure a clinical decision support intervention in method A for all required ONC items: problems, medications, allergies, labs, vitals, and demographics. The system achieves certification by demonstrating method A.

The system also includes a specialized method of clinical decision support (method B), which is focused on lab results only. Method B could not achieve certification independently because certification requires support for all criteria. However, method B is provided in the same system as method A. Providers who use this system and have the ability to use both methods A and B want to understand if they can consider interventions created with method B as clinical decision support for meaningful use.

It makes sense that CMS ensures that providers have access to systems that can at least meet all of the parts of certification. But, if that requirement limits providers to only those features, and only to "*certified modules*," and CMS limits providers to only method A, that will make certification a ceiling, not a floor. It limits the provider to use a feature that cannot be certified (i.e., because it is customized for a particular area). It also seems counter to CMS' general statements that providers are free to use many types of clinical decision support specialized for their workflows.

We suggest that CMS preserve provider flexibility in these scenarios and reconsider the guidance given in the final rule.

Objective 4 - CPOE
EHRA members are still uncertain about the CPOE imaging scope. We find both the previous definition and the revised definition unclear.

More than Ten Years of Advocacy, Education & Outreach 2004 – 2015   December 15, 2015

Objective 5 - Patient Electronic Access
CMS construes confusion over the time ranges for various objectives as due to misinterpretation by EHR developers. The statement that *"prior interpretation used by many developers contradicted this guidance and interpreted the lack of a time distinction in the numerator to mean that the action could occur at any point and was not constrained to the EHR reporting period or even the calendar or fiscal year"* is not accurate. EHR developers were specifically directed by CMS staff to read the regulation and the associated FAQ 8231 in this fashion, and some EHR developers have email guidance to this effect.

CMS should be clear that the change is a specific change in their policy and guidance. The effort that must go into reprogramming reports for the change is directly attributable to a failure on CMS' part to be clear in their regulatory guidance, and then inconsistent in informal direction offered by CMS to EHR developers. We do appreciate that CMS will allow current logic as reflected in the initial version of FAQ 8231 to apply through 2016, and urge that this point be very explicit in all applicable published measure specifications.

In addition, we anticipate that provider implementations of application programming interfaces (APIs) for patient applications will have many complexities that do not seem accounted for in CMS' requirements. For example, support of a large volume of applications pulling data from an electronic health record will have hardware implications, and providers will have to attempt to guess the volume of API usage and purchase servers accordingly to avoid slowing the performance of the EHR that their clinicians use.

Objective 6 - Patient Engagement
In measure 6.3, it is not clear why the objective measures *"non-clinical"* settings when the examples given do seem to be clinical in nature. Also, in many scenarios, the types of professionals mentioned do document directly in the EHR, in which case their documentation is structured and widely available to other clinicians. It is not clear why this objective seems to reward incorporating documents from other caregivers over having other caregivers document directly in the EHR.

Objective 7 - HIE
Providers are already asking many questions on what types of electronic transmission are permitted, including whether faxing is permitted. CMS should issue clear guidance on this issue, noting also that not all permissible transport methods a provider decides to use will be automatically counted by his or her EHR, which had not been designed or certified to measure the broader range of transport options now allowed.

We also have some confusion on the concept of self-referrals. Could CMS provide at least two examples of what would be a self-referral, as well as at least two examples of referrals that might be considered a self-referral but would not be, and how those four examples would be counted?

On measure 7.3, we note a discrepancy between the regulatory text language and the measure commentary. The regulatory text indicates providers have to meet two of three reconciled sets of information, while the measure commentary indicates all must be reconciled. We ask that CMS reconcile this discrepancy.

Objective 8 - Public Health
There are limited numbers of certification criteria applicable to this objective, and many providers will need to meet this objective using choices outside of certification. CMS should be clear to providers on when using non-certified capabilities is and is not permissible and, conversely, when certified capabilities must be used.

More than Ten Years of Advocacy, Education & Outreach
2004 – 2015