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June 25, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Proposed Rules [CMS-1599-P]

Dear Ms. Tavenner:

On behalf of the members of the EHR Association, we are pleased to submit our comments to the Center for Medicare and Medicaid Services (CMS) on the proposed rule, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Rates for Fiscal Year 2014 (proposed rule).

Established in 2004, the 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. This response was developed through an open, collaborative process engaging representatives from our member companies. The 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.

CMS is proposing an approach that begins to align the Hospital IQR and Medicare EHR Incentive Programs by providing hospitals currently participating in the Hospital

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IQR Program with the option of electronically reporting a subset of 16 measures that are already included in the 2014 version of the quality measures in the EHR Incentive Program. If a hospital chooses to electronically report these measures, they are required to report one quarter of CY 2014 quality measure data for each measure in order to meet their IQR quality measure obligations. CMS intends to also use this data to determine whether the hospital has satisfied the Medicare EHR Incentive Program quality measure reporting requirement. CMS also signals its intent to propose the requirement of electronic reporting for the IQR program beginning in CY2015 in future rule-making.

In this letter, we offer several comments in response to this proposed alignment in the proposed rule of the Hospital Inpatient Quality Reporting (IQR) program with the Medicare EHR Incentive Programs. Fundamentally, the EHR Association applauds the plans to align quality measurement across CMS programs. We also strongly support the CMS proposal to not require public reporting of the voluntary electronic IQR clinical quality measure data for 2014, along with the alignment of the 2014 reporting period for the voluntary IQR submission with the Medicare EHR Incentive Program. We also recommend that CMS not require public reporting of the IQR clinical quality measure data at least through CY 2015 to allow time to address the considerations detailed in this letter.

As we stated in our comments submitted to CMS on hospital and vendor readiness for EHR hospital inpatient quality data reporting in February, 2013, this alignment will greatly reduce the burden on both hospitals and the software developer community. Hospitals and other providers are challenged today with complying with multiple quality measurement programs as is the developer community as we strive to provide solutions for our customers. As we also noted in our February response, however, clinical quality measures (CQMs) are not yet optimized for electronic capture, calculation, and reporting. The electronic CQM (eCQM) specifications are based on retooled, manual quality measures. Many errors have been identified within these specifications. In addition, it cannot be assumed that the original, chart-abstracted measures align with the retooled eCQMs and produce comparable, consistent results. We also noted in our February 2013 comments that the QRDA Category I and Category III standards for transporting quality measures and associated data to CMS and others are relatively recent HL7 standards, with no broad-based testing of these standards.

Below, we offer detailed comments on several issues.

Consider the Complexity of Moving from Manual Abstraction to EHR-based Quality Measures

We make several suggestions related to the transition to EHR-based clinical quality measures. Our main point is to allow enough time for work to be completed and validated relative to this shift. *To this end, we call for a continued policy of not requiring public reporting of the eCQM submissions during 2015.*

Alignment between measure programs can lead to improved synergies over time. However, the level of complexity in the migration of clinical measures from chart abstraction to the EHR-based extraction methodology cannot be underestimated. Time and resources are required to assess current workflows, identify data capture gaps, reengineer processes, test reports, validate data, and train clinicians to document properly. During this period of transition to electronically captured quality data, organizations should be given time to make these changes so that accurate and reliable data can be reported.

In addition, more time should be allowed in the transition to fully research the implications of adoption of EHR-based extracted measures versus chart abstracted measures for quality reporting programs. Although there is recognition that the intent of a quality measure remains consistent between manually-abstracted and eCQMs, the final outcome will often have differing results. This variation follows from the significant differences between the measure specifications, collection process, and clinical workflow.

When used for public reporting, as well as for value-based payment, these differences can lead to confusion as most individuals are not aware of the difference in abstraction methods or why results would differ.

Confusion between the two types of measures has already been evident. Recently a discussion on the ONC Project Cypress “talk list” highlighted the confusion resulting from the similar titles used for chart abstracted and eCQMs. Retirement of manually-abstracted measures in the IQR program was assumed to mean that these measures are also being retired for the Meaningful Use program due to similar measure titles for both programs. This type of confusion should also be anticipated when measures are publically reported. *Alignment between reporting programs should include close attention to consistency in terminology use, as well as robust education for both the provider community and for the public before EHR-based extracted measures are publically reported.*

Clarify the Required Submission Formats for Both Programs

As written in the proposed rule, CMS has determined that the Quality Reporting Data Architecture Category III (QRDA-III), which reports at an aggregate level, is not feasible as an electronic submission format in 2014 for the Medicare EHR Incentive Program and that Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) would have the option to continue to report aggregate CQM results using attestation rather than electronic submission of QRDA data files. However, the submission of aggregate CQM data via attestation would not satisfy the IQR reporting requirements.

The EHR development community is very interested in why QRDA-III for aggregate submission has been determined not to be feasible for hospitals in 2014. Is there more information available for EHR developers, who are interested in following the adoption of this format and understanding if this feasibility assessment will change in 2015 and beyond? What makes the format feasible for individual states to implement but not for CMS?

We previously understood that for the Medicare EHR Incentive Program, EHs and CAHs had two reporting options, and now seek additional clarification on these options. The first option was to submit aggregate level data using QRDA-III and the second option was to report patient-level data using the Quality Reporting Data Architecture Category I (QRDA-I) format. Would the EH/CAH be required to submit both the aggregate CQM results using attestation and the patient-level data using the QRDA-1? Or would the hospital be able to select one of these methods?

The EHR Association has previously advocated for use of an aggregate electronic reporting method. QRDA-III, as an aggregate format is less complex than QRDA-I and requires less parsing and significantly smaller volume of data. It also more closely matches the attestation reporting that hospitals in the EHR Incentive Program are accustomed to, and would seem to build well on that experience. We urge that QRDA-III acceptance be revisited and offered as an option for 2014 reporting. Supporting QRDA-III for electronic submission in 2014 seems aligned well with the overall goals of encouraging electronic submission and aligning programs. In addition, as QRDA-III file generation is already part of the 2014 certification, hospitals will be well-equipped for this type of submission. If some states use QRDA-III for their electronic quality reporting, it will be convenient for hospitals in those states to be able to consistently report the same type of file for both their Medicare and Medicaid submissions.

Continue to Refine the Development and Testing of eCQMs

The EHR Association applauds the effort made by ONC and CMS to improve the eCQM development process that began in January 2013, and recommends that continued focus and time be devoted to this effort in order to realize significant improvements. As we have stated in past comments, CMS and ONC should continue to invest in quality measure alignment, infrastructure, and standards. Building on the

foundation begun with Stage 2 of meaningful use, this process should incorporate the time needed for establishing the necessary standards, field testing, and collaboration among measure developers. We cannot apply short-cuts to the rigor of this development process, which is critical to the measurement of quality and outcomes in healthcare as we move toward the alignment of EHR-based reporting and hospital quality reporting programs.

The EHR Association also supports the efforts by CMS and ONC to ensure that EHR solutions are tested for accuracy in the calculation of clinical quality measures (CQMs). Unfortunately, as we have communicated to the Office of the National Coordinator for Health IT (ONC) in both January and April of this year, we remain concerned that the current quality of the Cypress testing tool, test methods, and test data is inadequate to ensure data accuracy.

Cypress is described as the “gold standard” certification testing tool for Meaningful Use Clinical Quality Measure reporting and is the standard of accuracy against which all EHR systems undergoing certification testing are compared. This key role demands that Cypress must undergo thorough testing to assure its accuracy. However, a significant number of issues have been identified with each new version of testing tools. The EHR Association reiterates our request that each new version of the Cypress tool and the associated test methods and test data undergo thorough testing to assure accuracy including pilot testing, prior to general availability for certification testing.

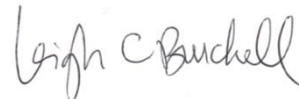
Conclusion

As always, the EHR Association appreciates the opportunity to provide feedback on the proposed alignment of the hospital IQR program with the CQM component of the EHR Incentive Program outlined in the proposed rule. We look forward to our continuing engagement as we work toward our shared goals of maximizing the important role that EHRs can play in the collection and reporting of clinical quality measures.

Sincerely,



Michele McGlynn
Chair, EHR Association
Siemens



Leigh Burchell
Vice Chair, EHR Association
Allscripts


HIMSS EHR Association Executive Committee



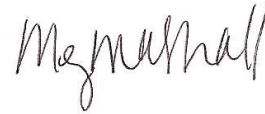
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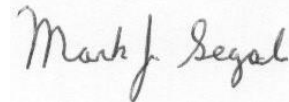
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About HIMSS EHR Association

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 the Healthcare Information and Management Systems Society (HIMSS). For more information, visit <http://www.himsshra.org>.