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September 5, 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

Dear Ms. Tavenner,

On behalf of the members of the Electronic Health Record (EHR) Association, we are pleased to submit our comments to the Center for Medicare and Medicaid Services (CMS) on the proposed rule, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014.

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.

We offer the following detailed comments in response to several specific areas of the proposed rule: the proposed alignment of the Physician Quality Reporting System (PQRS) with the electronic clinical quality measure (CQM) component of the EHR Incentive Program, proposed revisions to the PQRS, and proposed changes to the EHR Incentive Program as described in the proposed rule.

September 5, 2013

Overall, we would like to emphasize the following points:

- The Association strongly supports alignment of quality measures and reporting requirements across government agencies and, eventually, across private sector programs. The burden on both providers and vendors created by multiple reporting formats and standards, dual certification/qualification programs, and mismatched reporting periods and data submission timelines distracts key resources from achieving our shared goal of more efficient, accurate, and actionable information in order to improve care quality and outcomes.
- We generally support using qualified clinical data registries, given the alignment with other CMS quality programs, especially for the EHR Incentive Program. We have concerns about the ability of registries being used for PQRS reporting to use quality measures other than current PQRS measures, and/or National Quality Forum (NQF) endorsed measures, including “measures used by boards or specialty societies; and measures used in regional quality collaboratives”, which remain largely untested.
- In our view, it is too soon to require reporting entities to publically post performance data on measures reported through an EHR. Additional work should be done to verify the validity and accuracy of the measure results, as the performance scores may not be truly indicative of the quality of care delivered by some provider organizations.
- We are concerned about the proposal that eligible professionals (EPs) must use the most recent version of the electronic measure specifications, and we strongly recommend that updates be limited to very minor changes that would not require new software versions and certification. Adequate time and resources should be allocated to fully test all new eMeasure specifications before including them in any of the CMS programs, as well as thorough testing of the Cypress testing tool, test methods, and test data. We agree that practices providing complex chronic care coordination services must be using a certified EHR for beneficiary care, and that the EHR must be integrated into the practice to support access to care, care coordination, care management, and communication.

We elaborate on these points below.

A. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System (78 FR 43356)

In the proposed rule, CMS states that alignment of CMS quality improvement programs is critical for programs involving physicians and other EPs, and that this alignment will decrease the burden of participation on physicians and allow them to spend more time and resources caring for beneficiaries. The EHR Association applauds the current and proposed efforts to align quality improvement programs across CMS programs, including the PQRS and the EHR Incentive Program.

More generally, the EHR Association also supports alignment of performance measurement across all federal programs and more broadly across the private sector through the use of the same and/or harmonized measure specifications and reporting requirements. As we have previously responded in comments submitted to CMS on several occasions, we agree that this alignment will greatly reduce the burden on both providers, who today are challenged with complying with multiple quality measurement programs, and the vendor community, as we strive to provide solutions for our customers. Overall, we endorse a harmonized and feasible consolidated approach to reporting across multiple programs, and specifically the PQRS and EHR Incentive Programs with other federal and non-federal quality programs.

We also recommend that CMS consider additional ways to increase the alignment of PQRS and the EHR Incentive Program. Our customers have told us that physicians already view the PQRS program as complex and burdensome.

The EHR Association is also concerned about the additional burden on providers and EHR vendors who must comply with multiple reporting formats and standards, dual certification/qualification programs, and mismatched reporting periods and data submission timelines for participation in all programs. For example, in CY 2014, EPs must report for a full year for the PQRS, but are only required to report for one quarter for the meaningful use program. The EHR Association recommends that there should be a consolidated approach to reporting across these programs, which would include the alignment of reporting periods and data submission timelines. The need for technical alignment of quality measure specifications and reporting is critical and will greatly reduce the burden on EPs, while assuring data quality.

B. Proposals Related to Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals (78 FR 43360)

The American Tax Payer Relief Act of 2012 provided for a new standard for individual EPs to satisfy the PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry. In this proposed rule, CMS provides additional information including the proposed requirements for qualified clinical data registries for both the PQRS and the EHR Incentive Program.

The EHR Association provided recommendations to CMS on its request for information on the “Use of Clinical Quality Measures Reported Under PQRS, the EHR Incentive Program, and Other Reporting Programs,” and greatly appreciates that much of our feedback on reporting using a qualified data registry appears to have been incorporated into this proposal. The requirements for a qualified data registry seem comparable to other registry requirements for CMS quality programs, and reasonable, especially for the EHR Incentive Program, including use of the QRDA reporting standard. We are concerned, however, about the ability of registries being used for PQRS reporting to use quality measures that are not current PQRS measures and/or NQF-endorsed measures, including “measures used by boards or specialty societies; and measures used in regional quality collaboratives.” Most if not all of these measures have not been specified as e-measures and may not be capable of accurate representation in an electronic reporting format such as QRDA or XML. In addition, if they are not NQF-endorsed, they may not have undergone accurate validity and reliability testing, and may not be appropriate for use in other CMS programs such as the Value-Based Modifier program or the EHR Incentive Program.

For purposes of EHR Incentive Program Qualified Clinical Data Registry reporting, we strongly agree with the additional requirements proposed by CMS, including:

1. The EP must use certified EHR technology (CEHRT) as required under the Medicare EHR Incentive Program;
2. The CQMs reported must be included in the Stage 2 final rule and use the same electronic specifications established for the EHR Incentive Program;
3. An EP must have CEHRT that is certified to all of the certification criteria required for CQMs, including certification of the qualified clinical data registry itself for the functions it will fulfill (for example, calculation, electronic submission);
4. An EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR module that is part of the EP’s CEHRT.

We also ask that CMS confirm that certified EHRs have no obligation to support qualified clinical data registry reporting.

C. Public Reporting of Physician Performance Data (78 FR 43353)

CMS proposes to publically post the performance rates of EPs participating in the PQRS on the Physician Compare website in 2014, including those results that were reported through an EHR. The EHR Association believes that it is too soon to require reporting entities to publically post performance data on measures reported through an EHR, using the electronic clinical quality measure (eCQM) specifications and the Quality Reporting Document Architecture (QDRA) standards. Additional work should be done to verify the validity and accuracy of the measure results, as the performance scores that CMS will post may not be truly indicative of the quality of care delivered by some provider organizations.

Electronic 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. The EHR Association has also noted in past 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.

D. Reporting of Electronically Specified Clinical Quality Measures for the Medicare EHR Incentive Program (78 FR 43481)

CMS has proposed that EPs who seek to report CQMs electronically under PQRS and also under the Medicare EHR Incentive Program must use the most recent version of the electronic CQM specifications and have certified EHR technology (CEHRT) that is tested and certified to that most recent version. CMS has invited public comment on whether there would be sufficient time for EHR technology developers to update their systems and distribute the updated CQM versions in a timely way that would enable EPs to report using the updated versions. Additionally, CMS invited comments on whether there are any data or logic dependencies in the eCQMs that EHR technology developers have experienced which, if not built in upfront and deployed before a reporting period, would result in inaccurate measures, if for example, an EHR technology was upgraded in the middle of an EP's reporting period to the newest version of the CQMs.

Overall, we have substantial concerns about this requirement to use the most recent version of the specifications, as well as requiring CEHRT that is tested and certified to the most recent version. For the reasons outlined below, we think that this requirement will impose a major burden on both vendors and providers.

We also ask for clarification on whether EPs opting to submit quality measure data via attestation on the CMS portal because their EHRs have not been certified for the most recent CQM version will still have to attest using the same timeframes described in the Stage 2 EHR Incentive Program final rule, which stated that, although meaningful use objective attestation can take place throughout 2014, electronic submission of CQM data and thus completed attestation for providers after their first year of payment cannot take place until January 1, 2015 at the earliest. It will be important for both providers and EHR developers to understand if earlier meaningful use attestation and payments will be available for EPs either through electronic submission or attestation to CQMs. In this regard, we note that, in the recently released Final Rule for the Inpatient Prospective Payment System, CMS finalized revised submission periods for CQM data. For FY2014, they stated that the submission period for EH CQM data submitted electronically will now begin on January 2, 2014, and end on November 30, 2014. We also ask CMS to clarify whether the submission period for CQM data for eligible providers (EPs) will also be adjusted accordingly, so that EPs could submit data beginning on April 1, 2014 and end on January 30, 2015.

The EHR Association offers several specific examples of extensive data and logic updates that could impact the ability of software technology vendors and providers to implement these updates in a timely manner, as well as potentially reduce the validity of the measures if upgraded in the middle of the EP's reporting period.

1. Major changes to the Value Sets:

- In the final December 2013 CQM specifications, all of the value sets that contained allergy information provided the allergies at the RxNorm terminology type for a "Semantic Clinical Drug" (SCD). This is equivalent to a very specific medication dispensable, for example, "97449: Cefaclor 500 mg Oral Capsule". This was very problematic in terms of ensuring that allergies and allergy alerts were coded correctly due to the granular nature of the coding, and it was agreed by all stakeholders that this must be updated as soon as possible in all of the value sets.
 - This update for the value sets for allergies was implemented in the April 2013 CQM specifications, so that allergies are now defined at the correct RxNorm terminology type level, for example, "2176: Cefaclor".
 - While the change was welcome and more representational of how allergies are entered and recorded, software technology vendors were required to implement software changes in order to update the calculations for the clinical quality measures.

2. Changes to measures logic:

- CMS 123 – DM Foot Exam: Updated logic to require Visual Inspection, Pulse Exam, AND Sensory Exam

3. Extensive changes to a measure specification, including value sets and logic:

- CMS69v2 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up: The new version of the measure specifications included five new value sets, nine updated value sets, and removed ten value sets. Logic changes were extensive with updates to numerator 1, numerator 2, initial population 1, and initial population 2.
- For example, the value set for "Referrals where weight assessment may occur" has 31 new entries that need to be incorporated into clinician workflow and may require nomenclature mapping updates.
- In addition, the changes to the logic require software code changes in order to update the measure calculations.

We have provided some examples of updates that could be challenging and require more time than allowed given the current schedule of receiving EH CQM specification updates in April, and EP CQM specification updates in June. Although we find it difficult to provide every example of the type of updates that would or would not be problematic, we can generally say that minor changes in value sets (for example, a medication is removed from a value set because it is no longer on the market or a SNOMED CT code is added) are not difficult to implement since these changes typically do not have a significant impact on clinician workflow or require software changes.

Any major changes to value sets, and additions or deletions of full value sets can have a significant impact on clinician workflow and can often require software changes. In addition, changes to measure logic may also require software changes that will require additional time to address all necessary steps. With any major changes, vendors would require adequate time to identify gaps in data capture, implement and test software changes, certify the updated EHR software, and deploy updated software

to the providers, including providing any education to our customers on the impact of software changes to workflows. In addition, providers must have adequate time to assess current workflow, reengineer processes, test reports, validate data, train clinicians on any new workflows or documentation required, and provide additional education to their users.

The current six month window from release of the updated specifications to actual use in an EHR for both the EH and EP measures does not allow enough time to accommodate any major changes as identified above. In addition, as illustrated in the attached CQM development timeline, in order to accommodate specification updates issued annually, we note that it will be necessary for CMS to be able to accept two different specification versions during any identified overlap periods. For example, if a provider were to submit measure data for 2014 in January 2015, it must be acceptable to electronically submit either files using the June 2013 specifications (required) or the June 2014 updated specifications, and CMS must be able to accept both formats.

The EHR Association strongly recommends that CMS ensure that updates are as minimal as possible, and reflect the minor changes as discussed previously. In addition, most of the major updates that were necessary to the December 2012 CQM specifications were a result of numerous errors identified in the specifications. Accurate specifications, preferably using de novo measures, are critical to ensuring data validity, feasibility, and accuracy. We also strongly recommend that, prior to introducing new quality measures and specifications to any of the CMS programs, adequate time and resources be given to fully test all new CQM specifications.

Although the EHR Association supports the efforts by CMS and the Office of the National Coordinator for Health IT (ONC) to ensure that EHR solutions are tested for accuracy in the calculation of CQMs through the certification process, we do not believe that the updated measures should require re-certification, consistent with the position that CMS currently has in place [see CMS FAQ#8898].

Finally, as we have communicated to ONC in both January and April of this year, we remain greatly concerned that the current quality of the Cypress testing tool, test methods, and test data is inadequate to ensure data accuracy and has not undergone the necessary testing prior to general release. Cypress is described as the “gold standard” certification testing tool for meaningful use CQM reporting, and is the standard by which all EHR systems are compared. Nonetheless, a significant number of problematic issues have been identified with each new version of Cypress testing tools, test bundles, and certification test methods. We reiterate our previous comments and recommend that thorough testing, including the use of pilot sites, of every new version of the Cypress tool and the associated test methods must take place in order to assure accuracy prior to the availability of the Cypress software and testing tools for certification testing.

With the release of Cypress 2.4 on September 5, 2013, vendors will have received at least five releases of the software with accompanying changes to the certification test methods and test bundles in the last eight months. We strongly recommend reducing the frequency of the Cypress updates, in order to reduce the burden of implementing and testing each release. Assuring a quality product by implementing more stringent testing of the measure specifications, Cypress tool, and the test methods will help alleviate the need for such frequent updates to address software and measure testing defects.

Conclusion

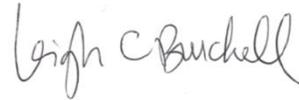
As always, the EHR Association appreciates the opportunity to provide feedback on those aspects of the Medicare physician payment system that are relevant to our members’ offerings, including alignment of the Physician Quality Reporting System (PQRS) with the electronic clinical quality measure (CQM) component of the electronic health record (EHR) Incentive Program, the proposed revisions to the

PQRS, and the proposed changes to the EHR Incentive Program as described 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



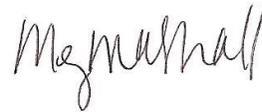
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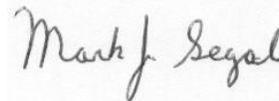
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About HIMSS EHR Association

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 www.ehrassociation.org.