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September 8, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Baltimore, MD 21244

Dear Administrator Slavitt:

Representing nearly 40 companies that develop electronic health records (EHRs) and other health information technology, the Electronic Health Record Association (EHRA) is pleased to provide comments on the proposed rule that updates payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS), [CY 2016 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B \(CMS-1631-P\)](#). We believe that EHRs and other health information technologies are foundational to healthcare payment reform, including new payment models based on outcomes and quality. The following comments reflect our collective experiences in working with hospitals and ambulatory organizations across the country on related initiatives.

Comments on Clinical Quality Measures Proposals

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) authorizes the end of the Physician Quality Reporting System (PQRS) in 2018 and the beginning of a new program which may incorporate aspects of the PQRS, the Merit-based Incentive Payment System (MIPS). As CMS begins to incorporate these provisions, they have stated their intention to continue the focus on aligning these requirements with other quality reporting programs such as the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals (EPs), the Physician Value-Based Payment Modifier (VM), and the Medicare Shared Savings Program.

EHRA strongly supports CMS' goal to align the clinical quality measure requirements of the MIPS with other Medicare and Medicaid programs. We agree that this alignment will eventually streamline the quality measure reporting process, reduce provider reporting burdens, and support the transition to a healthcare system focused on patient-centered outcomes measurement, quality improvement, and value-based care. We also support the use of electronic clinical quality measures (eCQMs) in these efforts.

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The industry is still in the early stages of migration from chart-abstracted and claims-based measures to electronic clinical quality measurement, and it is essential that CMS and ONC continue the work already in progress with multiple stakeholders to make improvements to the eCQMs, including the testing of infrastructure, the standards utilized, and the process for annual measure updates. Most recently, CMS has determined that a large number of errors or inadequacies have been identified in the QRDA I, QRDA III, and QCDR eCQM submission data, and is working with the vendor and provider communities to determine methods to resolve these issues. We have included several recommendations in our comments that we feel will assist in these efforts, as well as comments and recommendations on specific proposals in the proposed rule.

Physician Compare Web Site

In this proposed rule, CMS states that they will continue to expand public reporting on Physician Compare by making available a broader set of quality measures available for publication on the website in CY 2016. This expansion would include all 2015 Group level PQRs measures as well as all 2015 PQRs measures for individual EPs including EHR reported measures. *EHRA reiterates our previous comments that it is too soon to require reporting entities to publicly post performance data on measures generated and/or reported through EHRs, using the eCQM specifications and the Quality Reporting Document Architecture (QRDA) standards.*

EHRA has commented in the past on the lack of maturity of electronic submission of data using the QRDA, and recommended that CMS implement a pilot and validation plan in order to ensure the accuracy of the eCQM results. We are very concerned that public reporting of EHR-reported measures is not yet appropriate, specifically given the recent CMS findings of large numbers of errors in the eCQM submission data as noted above. CMS has publicly announced that these data do not meet public reporting standards of being valid, reliable, and comparable, and that because of this finding, 2014 EHR data will not be publicly reported on Physician Compare nor used to determine quality performance and/or establish benchmarks for the 2014 reporting year.

EHRA applauds this decision, and urges CMS to more generally delay public reporting of EHR-reported measures until the reliability and validity of the submission data can be assured, most immediately regarding 2015 data to be used or reported in 2016. We recommend that CMS continue the work started prior to and during the August 2015 Vendor Summit to determine the root causes of these submission issues, and to work with the vendor and provider communities on ways to mitigate such errors for future reporting periods. We also urge CMS to renew efforts to implement a pilot and validation plan in order to verify the validity and accuracy of the eCQM submission data, prior to publicly posting any performance scores or utilizing the results in the value-based modifier.

eCQM and Certification Criteria

CMS has reiterated its policy that once EHR technology has been certified to the CQMs, it does not need to be recertified each time an annual update is made to the CQMs. EHRA appreciates CMS continuing this policy. CMS also proposes to revise the certified EHR technology (CEHRT) definition under the 2015 edition to require providers to possess technology that can report CQMs using industry standards (QRDA Cat I and Cat III), *and in the form and manner of CMS submission (according to the CMS QRDA Implementation Guide (IG))*. This new certification criterion would be optional for 2015-2017, and required for 2018 and beyond.

EHRA has provided comments in the past to support this proposal, most recently in our comments to the IPPS proposed rule. In those comments, we also asked for clarification from CMS as to whether vendors would be required to certify to both the base QRDA standard, as well as the CMS

implementation guide. If so, we are concerned that this approach requires duplicate efforts, and we recommend that certification include only certifying to the CMS implementation guide, as this certification will assure our customers that their CQM data is in the form and manner specified and accepted by CMS. Vendors must implement the additional requirements in the CMS QRDA IG in order to provide the capabilities to our customers for electronic submission of eCQM data to CMS, and this will help assure providers that their CEHRT will support the electronic submission to CMS.

Regarding the proposed certification criterion that would require EHR technology to be certified to the CMS IG, we ask for clarification on the requirements for vendor certification. The CMS IG includes separate requirements for each eligible hospital (EH) and eligible professional (EP) quality program, such as the EHR Incentive program for EHs, the Inpatient Quality Reporting (IQR) program, the EHR Incentive program for EPs, PQRS, and the Comprehensive Primary Care Initiative (CPCI). As many vendors may target only the EH or EP constituency, and will not have customers that participate in all of these programs, we believe it is not feasible to include all of the various requirements within the certification criterion. In addition, these multiple program-specific guidelines add complexity to the submission process that can then result in increased implementation time by both vendors and providers, as well as potentially contributing to less accurate measure results. EHRA has recommended previously that the requirements for submission be aligned whenever possible, and we reiterate our recommendation to converge the program-specific form and manner requirements so that there is minimal variation.

We also note that this process will only be possible if CMS publishes the implementation guides for each of their programs with sufficient advance notice for products in use across the industry to pursue certification. Publication of an implementation guide late within the reporting year itself will not provide sufficient time.

EHRA also appreciates the clarification by CMS that once the EHR technology has been certified, it does not need to be recertified each time an annual update to the form and manner requirements (QRDA IG) is made. We provide the following recommendations to enhance CQM certification and to help address the recent findings of large numbers of errors in the eCQM submission data and to prevent such future negative outcomes:

- Timing of the annual eCQM measure updates as well as the release of any new eCQMs should be tightly coordinated with the release of updates to the CMS implementation guide (which we assume will cover multiple CMS quality and incentive programs), as well as revisions to the validation tools used for electronic submission. This linkage should include adequate time for implementing any changes. Considering the short timeline between publication of the payment rules and the required usage dates, EHRA reiterates our recommendations that annual updates and revisions be limited to minor changes, which do not have a significant impact on clinician workflow or require software code changes or recertification of the EHR software.
- Currently, there are three different validation tools, which all are intended to validate the QRDA submission files in different ways (Cypress QRDA certification tool, optional Cypress certification to the CMS IG certification, and the PQRS Submission Engine Validation Tool (SEVT)). This set of multiple tools causes a great deal of confusion to the provider and vendor communities. There is also an expectation that any validation tools used would assure the vendor or provider of a high level of accuracy in the eCQM submission data but, as noted previously, the review by CMS of the submission data revealed a high number of errors. EHRA strongly recommends that there should be a single validation tool for EPs and one for EHs, or at least the fewest needed to implement CMS and ONC policies; and that any validation tools incorporate the necessary changes to address the recent findings of significant errors in the CQM submissions for the 2014 reporting year and in general to flag the full range of foreseeable submission errors.

- As discussed at the Vendor Summit, we also urge that CMS and ONC take more focused care to develop CQM-specific test data sets that are tuned to the specific CQM in question, while also maintaining the current approach of keeping test data sets as small as possible to reduce testing burden. These more finely tuned test data sets will enhance the ability of certification and validation tools to increase the accuracy of specific CQM calculations.
- Both the implementation guide and the validator(s) should include any requirements for successful submission of the eCQM data. The large number of errors identified that were caused by requirements for submission that were NOT included in the certification process using Cypress, the CMS implementation guide, or the validators could be avoided if this were the case.

EHRA notes that there have been frequent revisions to the requirements for eCQM submission, including changes to the Cypress certification tool, updates to the version of QRDA expected to be utilized, and updates to the CMS implementation guide. In CY 2015 alone, revisions were made in January, April, and June. As noted in both the final IPPS rule and this proposed rule, we are anticipating further changes to these requirements. It is difficult for a vendor or provider to identify all the relevant documents and information to ensure that they are utilizing the most recent requirements. We provide the following recommendations to CMS to help address these issues:

- Continue to utilize and enhance the eCQI Resource Center launched this year as a “one-stop” area to include all relevant information and documentation related to the eCQMs. In the past, it was difficult to locate all relevant locations and websites for the numerous revisions of documents and specifications necessary to ensure accurate implementation of the eCQM quality reporting requirements.
- Reduce the number of revisions to the requirements, tools, and documentation for eCQM certification, validation, and submission in a given calendar year. These numerous revisions lead to missed information by vendors and providers, resulting in errors such as the ones identified in the eCQM submission data. Many of these revisions are a result of inadequate testing and piloting of the eCQMs, as well as the submission process, including the standards and tools utilized. EHRA has provided numerous recommendations in the past regarding the need for more testing and piloting of the eCQMs, the standards utilized, and the submission process. We reiterate the importance of this testing and validation process prior to requiring the use of new and revised eCQM specifications, along with the associated standards and tools.

Comprehensive Primary Care Initiative (CPCI) Expansion Request for Comment: Quality Reporting

CMS states that they are interested in comments on practice readiness to report eCQMs, and payer interest in using practice site-level data rather than their own enrollees’ information for performance-based payments, including shared savings, in a potential expansion of the CPC initiative.

EHRA is concerned that it is too soon to utilize the eCQM data for an expanded approach to performance-based payments, especially given the quality issues discussed above. At the same time, the impending implementation of MIPS, with 2019 payments likely affected by 2017 CQM data, underscores the urgency of learning from the 2014-15 experience and acting on recommendations like those made by the EHRA and discussed at the Vendor Summit. We reiterate our recommendation to delay public reporting of EHR-reported data for use to determine quality performance until the reliability and validity of the data can be assured. We have provided recommendations on this topic in our preceding comments.

Comments on Alternative Payment Proposals

Establishing Separate Payment for Collaborative Care

CMS believes that the care and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information sharing, and planning among primary care physicians and specialists. CMS is seeking comments on how Medicare might accurately account for the resource costs of a more robust inter-professional consultation within the current structure of PFS payment, as well as on key technologies needed to support collaboration among specialists and primary care practitioners.

If CMS moves forward with a new payment structure for collaborative care that includes technology requirements, EHRA encourages CMS to leverage requirements from existing programs, such as meaningful use, to minimize the burden on providers. In general, the EHRA recommends harmonizing technology requirements across programs to streamline compliance efforts by providers and vendors. We also urge that CMS not seek to add additional certification requirements for new collaborative care payments, but rather recognize the appropriate variability in appropriate solutions, including the level and nature of technology used.

MIPS – Clinical Practice Improvement Measure

Clinical practice improvement activities are defined as activities that relevant EP organizations and other stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. CMS is asking for comment on what activities could be classified as clinical practice improvement activities according to its definition which includes expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in an alternative payment model. The EHRA provides the following guidance to CMS in defining the clinical practice improvement measure:

- Ensure that the specified activities apply to both specialists (recognizing the range of specialties) and primary care providers.
- Leverage work done with PQRS and other programs.
- Consult with the EHRA and other experts on ways to streamline measures and leverage technology that is consistently available in the market, across vendor platforms.
- Evaluate technology standards for stability, maturity, and widespread adoption before incorporating them into clinical practice improvement activity definitions. For example, clinical decision support (CDS) is a key technology supporting population management and care coordination, and the EHRA supports including the use of CDS as a clinical practice improvement activity, as it is defined in meaningful use Stage 2. We do not support using the clinical practice improvement measure to promote the adoption of immature CDS initiatives, such as HealthDecisions, prior to mainstream adoption of such initiatives.
- Do not seek to require additional certification for technologies to be used for improvement activities. As with collaborative care payments, recognize the appropriate variability in appropriate solutions, including the level and nature of technology used.

Upcoming RFI re Alternative Payment Models (APMs)

In preparation to implement the changes introduced by MACRA, CMS intends to publish questions for public comment through a request for information (RFI) to obtain more input on its provisions, including increasing transparency of physician-focused payment models, criteria, process for submission, and review, incentive payments for participation in eligible alternative payment models, encouraging development and testing of certain models, a study on integrating Medicare APMs in the Medicare

Advantage payment system, and study and report on fraud-related to APMs under the Medicare program. In anticipation of the future RFI and subsequent notice and comment rulemaking, CMS is asking for comments on approaches to implementing any of these topics.

As new payment models are evaluated, EHRA encourages CMS to consult with us on technology capabilities under consideration as requirements of the new models to avoid situations where EHRs or other health IT cannot support the requirements placed on APM participants. We also recommend that EHR requirements be based on the use of CEHRT in order to leverage work done by providers to adopt CEHRT and to ensure the consistency of interoperability requirements it supports across provider practices, hospitals, and health systems.

MSSP Quality Measures

While CMS is not proposing any changes to the current measure “percent of PCPs who successfully meet meaningful use requirements” at this time, they are seeking comment on how this measure might evolve in the future to ensure that providers are incentivized and rewarded for continuing to adopt and use more advanced health IT functionality.

Should CMS decide to keep the measure the same, the EHRA supports including specialists that are accountable care organization (ACO) participants in the measure. We believe that care coordination is more effective when all providers on the ACO team are meaningful users of EHRs. Should CMS elect to modify this measure, we defer to the provider community on what they consider the most appropriate metrics for this portion of the accountable care program. We note that using metrics already employed in other programs, such as numbers of meaningful users, or re-using specific meaningful use metrics presents efficiency for providers as it does not require them to create new metrics or reports solely for this purpose. We also advise against creating any type of new program for measuring use of health IT which would create an incremental burden for providers and vendors beyond meaningful use.

Appropriate Use Criteria

We note that the schedule and process proposed for appropriate use criteria (AUC) is focused on the content of the criteria, and not on the technical standards that may be used, nor the method in which the content would be delivered. Given the timelines for implementation of the content, we urge that options for technical standards and how content is delivered be left open. In particular, we do not see the HealthDecisions standard as proposed in ONC 2015 edition certification earlier this year as sufficiently mature for this use case.

The Protect Access to Medicare Act (PAMA) outlines milestone dates that are key in the development of the provider-led entities, as well as dates that lay out the timeline for software developers to adopt and providers to implement the necessary capabilities to support the adoption of appropriate use criteria by January 1, 2017. These dates dictate an initial list of CDS mechanisms are provided by April 1, 2016. CMS has indicated in this 2016 Physician Fee Schedule proposed rule their intentions to release the initial list of specified applicable CDS mechanisms after the CY 2017 PFS final rule. This rule is scheduled to be released in November 2016. The proposed schedule allows less than two months for software developers and health IT implementers to understand the applicable CDS mechanisms, update their software to include the initial list, and implement the information across the industry for the start date of January 1, 2017. We are significantly concerned that the timeline that CMS proposes to follow leaves insufficient time for physicians to be in a position to comply by January 1, 2017. Certification of health IT used to support the adoption of AUC for ordering of diagnostic imaging is especially impractical on such a timeline, and the 2014 edition CDS criteria and associated interoperability standards are not well suited to support the necessary workflow.

We also urge CMS to consider the time needed to successfully implement the program, inclusive of finalizing the necessary interoperability standards and guidance, as well as vendor efforts to enter into business agreements for having access to the clinical content that will be required for CDS for presenting the AUC guidelines within clinical workflows for the ordering of advanced diagnostic imaging procedures. This also includes the need to develop or modify health IT products as needed, to make updates available to clients, and to allow sufficient time for clients to adopt these updates.

Additionally, CMS will presumably have to specify how the evidence of the use of given AUC guidelines for specific diagnostic imaging procedures need to be documented on the healthcare claim. There will be development work to enable communication of the AUC guideline reference from the system responsible for the ordering of the procedure through to the billing system.

We do applaud CMS in their intention to spend the appropriate time with the program to define the process by which organizations are recognized for the development of AUC guidelines. We appreciate that CMS is faced with a short amount of time from PAMA becoming law to when information could have first been released. We urge CMS to do what they can to accelerate the timeframe by which requirements may be known for health IT to support AUC implementation and adoption, or to delay the program effective date to a more reasonable timeframe. We also urge CMS to develop an approach that serves to expedite the recognition of AUC developers and the promulgation of implementation guidance for vendors and their provider clients that best supports industry readiness by the statutory dates.

In the longer term, we see the work of the Clinical Quality Framework as promising, and do think that the industry will want to move to standardizing methods by which content authors following the process proposed by CMS could standardize their material so that it could be incorporated into many different types of systems, such as EHRs and other health IT.

Certified EHRs and Chronic Care Management (CCM Certification)

EHRA supports the proposal to require use of the edition of CEHRT required the prior year by the EHR Incentive Program.

CMS proposes that no specific type of electronic solution or format is required to meet the expectation of an electronic care plan, but encourages consideration of standards proposed in the 2015 ONC edition certification criteria. We agree that the technical format of the care plan is best left open at this time.

CMS also proposes that certified health IT must be used for “the recording of demographic information, health-related problems, medications, and medication allergies; a clinical summary record; and other scope of service requirements that reference a health or medical record” (page 41796). We assume that this would correlate with the following certification criteria, which seem appropriate:

- §170.314(a)(3) Demographics
- §170.314(a)(5) Problem list
- §170.314(a)(6) Medication list
- §170.314(a)(7) Medication allergy list

There are several certification criteria related to clinical summaries, but given the program’s emphasis on coordination among healthcare professionals, the most appropriate criteria seem to be:

- §170.314(b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries
- §170.314(b)(2) Transitions of care – create and transmit transition of care/referral summaries

Table 17 on page 41797 lists several additional functions that are expected to be done using CCM certified technology, but that are not within the scope of the certification criteria currently published by ONC, including (1) documenting provision of the care plan to the beneficiary, (2) documenting communication to and from home and community-based providers regarding the patient's psychosocial needs and functional deficits, and (3) documenting the beneficiary's written consent and authorization. Given that no certification is currently available for those functions, CMS should clarify by either removing the reference to using CCM certified technology for these items, or by explicitly saying that the same software as is used for recording demographics, problems, medications, and allergies is expected to be used for these additional documentation functions.

We look forward to working with CMS and other policymakers to ensure that health IT, and EHRs specifically, is considered as we work collaboratively to transform our healthcare system to the benefit of all Americans.

Sincerely,



Leigh Burchell
Chair, EHR Association
Allscripts



Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

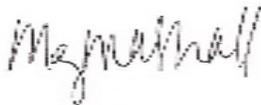
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About the EHR Association

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.