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September 2, 2014

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: CMS-1612-P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule

Dear Ms. Tavenner:

On behalf of the members of the Electronic Health Record Association (EHRA), we are pleased to submit our comments to the Center for Medicare and Medicaid Services (CMS) on the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule.

Established in 2004, EHRA is comprised of nearly 40 companies that employ industry experts in the field of health information technology (HIT) with a broad scope of expertise, such as physicians, nurses, pharmacists, technologists, and policy experts. These individuals not only represent the EHR software industry, but also interact with and reflect the breadth of the entire healthcare community. We support the majority of hospitals and practice-based physicians in organizations of varied sizes and specialties that are using digital records to deliver care to their patients. This response was developed through an open, collaborative process engaging representatives from our member companies.

We offer the following comments and recommendations in response to several specific areas of the proposed rule: the use of Certified Electronic Health Record Technology (CEHRT) for Chronic Care Management (CCM); the alignment of the Physician Quality Reporting System (PQRS) with the electronic clinical quality

measure (eCQM) 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.

Requiring the Use of CEHRT for Chronic Care Management (CCM)
CMS proposes to require the use of 2014 edition CEHRT, including an electronic care plan, in order to qualify for chronic care management reimbursement, with certification to a minimum specified set of 2014 criteria. *EHRA generally agrees that using CEHRT will help ensure that providers have access to critical patient information such as problems, medications, and allergies, and that communication among providers may be further facilitated by electronic exchange of a summary of care record.* These capabilities are already required as part of 2014 CEHRT, and providers are utilizing them to demonstrate meaningful use.

We do want to be clear on a concern based on the pending release of the Final Rule for the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria, which is now titled "2014 Edition, Release 2". We urge in the strongest possible terms that no criteria beyond those capabilities that are included in the initial 2014 edition be required for qualifying for the CCM reimbursement. The addition of any new certification criteria not tied to the EHR Incentive Program and 2014 edition CEHRT would impose a considerable burden on providers, many of whom are only now just implementing and beginning to use the 2014 edition EHR software. In addition, any additional certification criteria outlined in the Voluntary Certification Final Rule is not required for the EHR Incentive Program, and compliance is voluntary for that program, as stressed many times by the Office of the National Coordinator (ONC). We urge CMS to consider only those certification criteria required by the EHR Incentive Program within the CCM requirements.

To that end, EHRA is also concerned that the proposed new scope of service requirement for electronic care planning capabilities goes beyond the current requirements of CEHRT. We provided comments previously on the feasibility of a shared electronic care plan, most recently in response to the ONC Health Information Technology Policy Committees' (HITPC) Request for Comment for Stage 3. There are currently no standards in place to support a shared electronic care plan within an EHR. In addition, the development of innovative care management solutions may be better suited outside of what is currently considered an EHR, in order to accomplish these capabilities as part of longitudinal, coordinated care management. *EHRA agrees with CMS that allowing flexibility is important given the current immaturity of EHR standards and other electronic tools, and we strongly recommend that CMS continue to support this flexibility in the technology solutions used to accomplish care management, including the use of a shared electronic care plan, in order to allow the creation of more innovative solutions.*

Reporting of Physician Quality Reporting System (PQRS) Measures on Physician Compare
CMS proposes to publically post the performance rates of eligible professionals (EPs) participating in PQRS in 2015 on the Physician Compare website in late CY 2016, including results reported through EHRs. *EHRA reiterates our previous comments that it is too soon to require reporting entities to publically post performance data on measures generated and/or reported through EHRs, using the eCQM specifications and the Quality Reporting Document Architecture (QDRA) standards.*

There has been no experience to date with electronic submission of data using the QRDA, as CMS is not yet able to accept these submissions. *In addition, EHRA strongly recommends that CMS implement a pilot and validation process in order to ensure the accuracy of the eCQM results.* During the June 16, 2014 CMS meeting to discuss the annual measure updates, the agency suggested that new quality measures could be piloted by providers prior to requiring their use within a federal program. We urge CMS to implement this proposal, which would allow hospitals and physician practices more time to educate providers, adjust workflow, and ensure identification of any revisions needed to the eCQM

specifications prior to required use. Prior to requiring any public reporting of eCQMs, these steps are necessary 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 providers.

Physician Quality Reporting System (PQRS)

The Association strongly supports alignment of quality measures and reporting requirements across government agencies and, eventually, across private sector programs, as demonstrated through the PQRS and the EHR Incentive Program. 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.

At the same time, the CMS proposal to extend the deadline to submit quality measures data for qualified registries ***only*** concerns us, as this proposal does not seem to support that alignment. EHRA understands the large amount of time required to calculate quality measure results and to prepare the files necessary for reporting CQMs to CMS, which is the justification provided for extending the deadline for qualified registry reporting of quality measures to March 31st. However, we would like clarification on why this extension is being offered ***only*** to qualified registries and not to all reporting entities, given that the process required for EHR data submission vendors is very similar in time and resources to what is required of qualified registries. *EHRA proposes that CMS harmonize the reporting deadline for all reporting entities to March 31st to provide adequate time not only for the reporting entities, but also for CMS to process the growing volume of data that will be submitted as more and more providers select electronic reporting.*

CMS also poses a question concerning allowing more frequent submissions of data, such as quarterly or year-round submission*. EHRA asks for additional clarification around what is meant by "year-round submissions" for quality measure data.* We are concerned about the additional resource and technical requirements that would be needed to manage this flexibility, regardless of whether it is a requirement or an option for more frequent submission. We are also concerned about the technical challenges that this might cause when coupled with other quality measure work related to updating annual measures, certification and testing, and other related activities.

We recommend that CMS support quarterly reporting, as an option, in order to accommodate the large volume of data that will require uploading. This approach would be contingent upon having all other dependencies in place well before the end of the first quarter, including the release of the annual measure update and the QRDA Implementation Guides. We look forward to further discussion with CMS on the feasibility and requirements of implementing this proposal.

CMS also mentions the updated QRDA Implementation Guides and proposes that, for 2015 and beyond, the EP or group practice must provide the CMS EHR Certification Number of the product used by the EP or group practice for direct EHR reporting and EHR data submission vendors. *EHRA requests additional clarification on the method that CMS proposes to accomplish this requirement and opposes this requirement for QRDA submissions.* In previous conversations with CMS, we have provided information documenting the difficulty of an EHR vendor providing this certification number in the actual electronic transmission file, as the vendor does not have this information, and the provider receives it from the ONC CHPL site based on the final CHPL certification numbers of all of the certified EHR technology to be used in the provider's specific attestation, which may not be known until the time of attestation. We request clarification on how CMS intends to provide the capability for the EP or group practice to provide this number, and we welcome further discussion with CMS on the most feasible options.

Reporting of eCQMs for the Medicare EHR Incentive Program

EHRA applauds CMS' efforts to improve and streamline the annual eCQM update process, including the proposal in this NPRM that, beginning in CY2015, software developers would not be required to recertify their software to the most recent version of the electronic specifications. Most recently, in the 2015 IPPS final rule, CMS finalized their proposal that recertification would not be required for the updated eligible hospital (EH) electronic specifications for the Inpatient Quality Reporting (IQR) or EHR Incentive Program, and we urge CMS to provide the same flexibility for EPs.

Unfortunately, despite these provisions in recent payment rules, there remain pressing questions around the timing of measure specifications and the corresponding updates, as well as clarification and agreement among all stakeholders, including CMS, ONC, Authorized Certification Bodies (ACBs), and Authorized Testing Labs (ATLs) on whether certification is or is not required for the annual updates, including 2014 submissions. We refer CMS to the EHRA letter recently sent regarding the urgent need for clear guidance on this topic.

To summarize EHRA's concerns, which have been discussed in multiple meetings with the agency, the timing and magnitude of the changes to both the measure specifications and value sets, as well as the QRDA Implementation Guides, do not leave enough time to ensure implementation by providers prior to the beginning of the reporting year. In addition, recertification causes delays in delivery of updates to our customers, as well as requiring significant resources and additional expense in the development process that discourages both providers and EHR developers from staying current with CQM specifications.

These time constraints are magnified by the uncertainty of what will be required, as well as the fact that the Cypress version to support the annual measure updates is not scheduled for release until late September, with certification not being available for at least another month. In addition, the removal of the certification requirement for the EP annual measure updates is only ***proposed*** in the PFS proposed rule, which will not be finalized until much later in the year. This situation creates uncertainty and concern that EHR developers will have too little time to accomplish certification and subsequent implementation of software by EPs, even with everyone's best efforts.

We urge CMS and ONC to ensure that there is alignment between CMS, ONC, and the ATLs regarding not requiring certification for the annual updates (as stated in the recent IPPS final rule, and proposed in the PFS proposed rule), and to provide clear guidance on this topic as soon as possible, extending the 2015 policy to 2014 where applicable.

CMS also proposes that if errors are discovered in the most recently updated electronic measure specifications for a certain eCQM, the previous version of the specifications would be utilized. We commend CMS for taking this important issue into consideration. As observed with previous measure updates, errors have been identified after the official release of eCQM specifications. This situation reinforces the challenge of measure development in the absence of proper field testing, which also translates into increased costs for those attempting to implement eCQMs containing errors.

Nonetheless, due to the complexity of eCQMs and the interdependency of data elements and value sets, we do not recommend reverting to a previous version of a measure. Instead, if errors are found, the measure should not be used for the reporting period until fixed during the next annual update. One important example supporting our recommendation is the complex alignment of value sets during the annual update process. If value sets are repurposed across measures, changes will need to be made to EHRs in order to support the newer versions. Having multiple versions of a value set in use during the same reporting year is not feasible, nor is it ideal for accurate quality reporting. If the goal is to ensure

validity and reliability across reporting years, the focus should be on ensuring the eCQM updates are properly tested prior to their release. If errors are found, the measure should not be reported on until the specifications are corrected.

Regarding the requirement to use the most recent, updated version of the measure Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), if an EP chooses to report the measure electronically in CY 2015, we request additional clarification as to which version is expected to be used if the EP is manually attesting.

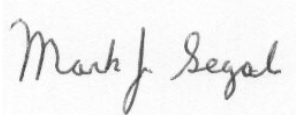
Medicare Shared Savings Program

CMS discusses the use of EHRs and other types of HIT to accelerate health information exchange (HIE), in order to improve care delivery and coordination across the care continuum. *Although EHRA strongly supports the use of EHRs and other HIT to support these critical activities, and we support voluntary certification for HIT that falls outside of the current definition for EHRs that support meaningful use, we oppose the increased burden and complexity introduced in the ONC 2015 Voluntary Certification proposed rule.* It is critical that providers are not overburdened by frequent software updates and workflow changes, and that vendors have the opportunity to create more innovative software capabilities. Optimizing the cadence and content of certification is an important opportunity to make HIT relevant across programs, while avoiding adding layers that are not manageable or efficient.

CMS also invites comments on the use of EHR-based reporting of quality measures in the Shared Savings Program. As we have stated previously, EHRA supports the goal of aligning quality improvement programs across federal programs. However, we are still in the early stages of electronic clinical quality measurement. The migration from claims-based or manually abstracted measures to EHR-based extraction methodology presents complexities related to standards, validity and reliability, and provider workflow considerations. We strongly support CMS' and ONC's efforts to improve the current standards used in the eCQM development and implementation process through the Clinical Quality Framework Initiative. As CMS and ONC work to align the quality programs, these improvements are critical to ensuring the reliability, accuracy and validity of the eCQM programs. *Because of the early stages of this work, EHRA believes that it is premature to consider implementing EHR-based reporting of quality measures in the Shared Savings Program.*

The Association appreciates this opportunity to provide comments on these programs as we participate in efforts to improve the processes and tools that support electronic clinical quality measure development and reporting. We look forward to ongoing collaboration with CMS and ONC, along with other stakeholders, as we strive to represent the shared experiences of EHR Association members and our customers.

Sincerely,



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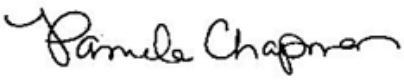

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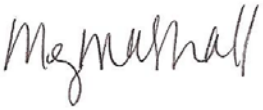

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About HIMSS EHR Association

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.