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December 19, 2016

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-FC
P.O. Box 8013
Baltimore, MD 21244-8013

We are pleased to submit these comments on behalf of the more than 30 member companies of the Electronic Health Record Association (EHRA) on the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Quality Payment Program. The collaborative efforts of our Delivery System Reform Workgroup, our Standards & Interoperability Workgroup, and our Public Policy Leadership Workgroup bring the expertise of many professionals who have long careers in the development and deployment of EHRs and other health IT in use in provider organizations across the US.

In particular, we suggest that CMS continue to establish data transmission formats for quality measures in conformance with the 21st Century CURES bill, which give deference to accepted industry standards published by standards development organizations (SDOs). This coordination across government agencies, SDOs, clinicians, and health IT developers will ultimately help us achieve our shared goals of a more interoperable, efficient healthcare delivery system for all Americans.

We look forward to working with CMS to ensure that these important regulations indeed achieve those objectives.

Sincerely,

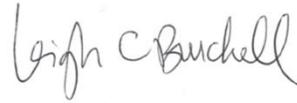
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About the EHR Association

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.

Electronic Health Record Association Responses to the Centers for Medicare and Medicaid Services (CMS) on Specific Questions in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Quality Payment Program

Group Reporting

Non-patient facing – Based on the comments received regarding the establishment of a separate non-patient facing threshold for groups, we are seeking additional comment on our modified policy for future consideration, which determines that a group would be considered non-patient facing if more than 75 percent of the NPIs billing under the group’s TIN meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period (pg. 158).

Identifiers - For future consideration, we are seeking additional comment on the identifiers. What are the advantages and disadvantages of identifying new Medicare-enrolled eligible clinicians and eligible clinicians not included in the definition of a MIPS eligible clinician until year 3 such as therapists? What are the possible identifiers that could be established for identifying such eligible clinicians (pg. 193)?

Exclusions - We welcome additional comment on: how we are applying the application of group-related policies pertaining to group-level performance assessment and scoring and the MIPS payment adjustment to groups with eligible clinicians excluded from MIPS based on the three exclusions or not MIPS eligible for the first 2 years of MIPS; the advantages and disadvantages of how we are applying the application of group-related policies when groups include eligible clinicians excluded from the requirement to participate in MIPS at the individual level; and alternative approaches that could be considered (pg. 256).

EHRA Response

MACRA has introduced new opportunities for eligible clinicians (ECs) to participate in MIPS as part of groups. While this option offers helpful flexibility for ECs who feel group reporting better reflects the organization of their practice, offering both group and individual reporting options for new areas will require additional work for CMS and health IT developers.

In particular, health IT developers need specifications for consistent group reporting. As this guidance is developed, it will need to include how group reporting applies to each objective in the Advancing Care Information (ACI) category. For example, group reporting would need to be implemented differently for the Patient Access to Health Information objective than for the Clinical Information Reconciliation objective because one objective can be met universally for a patient by a single provider and the other objective is encounter specific.

The development, certification, and implementation involved in group reporting for MIPS should be built into CMS’ timeline.

The policies and specifications for group reporting should also be created with the intent of remaining the same for future reporting years instead of being redefined each year. This stability would allow

health IT developers to confidently invest in report development and help ECs more reliably predict future outcomes with group reporting without the waste of resources created by frequent change. CMS specifically seeks comment on policies pertaining to exclusions for group reporting (pg. 77071). We support the current direction in the Final Rule to calculate the score for the entire group, including excluded providers, such as new Medicare-enrolled clinicians, qualifying participants (QPs), and partial QPs. This approach enables organizations to plan for future years when participation status might change, while accomplishing CMS's goals of encouraging coordination, teamwork, and shared responsibility (pg. 77071).

CMS also asks for comment on using an identifier so groups with ECs and non-eligible clinicians can participate. Both ECs and non-eligible clinicians reporting as part of a group should be identified by TIN/NPI, which is consistent with identification for individual reporting. We do not see a need for a separate identification system. Similarly, CMS seeks comment on identifiers for new ECs who will not be included in the definition of MIPS ECs until year three. CMS should identify these clinicians based on NPI/TIN to be consistent with how other clinicians are identified. Timing is a concern if changes to group reporting requirements are expected in 2017. Considering that 2014 and 2015 edition CEHRT can be used in 2017, EHRA recommends that CMS not change reporting requirements; but, if changes are to be made, information should be made generally available and disseminated immediately.

Virtual Groups

We appreciate the suggestions from the commenters and as a result of the recommendations, we are interested in obtaining further input from stakeholders regarding the types of provisions and elements that should be considered as we develop requirements applicable to virtual groups. Therefore, we are seeking additional comment on the following issues for future consideration: the advantages and disadvantages of establishing minimum standards, similar to those suggested by commenters as noted above; the types of standards could be established for members of a virtual group; the factors would need to be considered in establishing a set of standards; the advantages and disadvantages of requiring members of a virtual group to adhere to minimum standards; the types of factors or parameters could be considered in developing a virtual group framework to ensure that virtual groups would be able to effectively use their data for meaningful analytics; the advantages and disadvantages of forming a virtual group pilot in preparation for the development and implementation of virtual groups; the framework elements could be included to form a virtual group pilot (pg. 269).

We are seeking additional comment on the following issues for future consideration: the types of requirements that could be established for virtual groups to promote and enhance the coordination of care and improve the quality of care and health outcomes; and the parameters (for example, shared patient population), if any, could be established to ensure virtual groups have the flexibility to form any composition of virtual group permissible under the Act while accounting for virtual groups reporting on measures across the four performance categories that are collectively applicable to a virtual group given that the composition of virtual groups could have many differing forms (pg. 271).

We are seeking comment on the following issues for future consideration: the factors virtual groups would need to consider and address in order for the reporting and submission of data to be streamlined

in a manner that allows for categorization of datasets and comparison capabilities; the factors an individual clinician or small practice who are part of a virtual group would need to consider in order for their CEHRT to have interoperability with other CEHRT if part of a virtual group; the advantages and disadvantages of having members of a virtual group use one form of CEHRT; the potential barriers that may make it difficult for virtual groups to be prepared to have a collective, streamlined system to capture measure data; and the timeframe virtual groups would need in order to build a system or coordinate a systematic infrastructure that allows for a collective, streamlined capturing of measure data (pg. 273).

Therefore, we are seeking additional comment for future consideration on the following: the advantages and disadvantages of creating a new identifier for virtual groups; and the potential options for establishing an identifier for virtual groups. We intend to explore this issue (pg. 275).

EHRA Response

CMS requested comment on virtual group reporting, which is another new concept under MACRA. We found it challenging to comment specifically when the concept of virtual groups remains undefined. We envision two possible approaches to virtual group reporting:

- A virtual group that is a subset of a TIN. We expect that this type of group could be easily accommodated by currently available health IT.
- A virtual group that includes providers from multiple TINs. This scenario would require a new interoperability standard because existing standards do not include all of the data that would be needed to combine and de-duplicate data from multiple systems, especially for the ACI category.

If CMS intends for virtual groups to include providers from multiple TINs, it needs to adopt a standard to handle complex reporting situations.

As CMS further defines virtual groups, they should make every effort to design virtual group reporting to be consistent with other forms of group reporting. This includes the same approach to exclusions, reporting across categories, submission methods, and payment adjustments. Developing virtual groups, similarly to TIN group reporting, allows healthcare organizations and health IT developers to use the same tools in both cases.

CMS specifically requested comment on minimum standards for virtual groups. We suggest that all providers who participate in virtual groups be required to use 2015 ONC edition certified software so that the data can be consistently aggregated from multiple EHRs and use the same standards. Under the current rule, 2015 ONC edition certified software is required only for reporting on the ACI category. CMS also seeks comment on creating a new identifier for virtual groups (pg. 77076), and we agree that a new identifier would be necessary.

Quality Measures

Cross-Cutting Measures— We are seeking comments on adding a requirement to our modified proposal that patient-facing MIPS eligible clinicians would be required to report at least one cross-cutting measure in addition to the high priority measure requirement for further consideration for MIPS year 2 and beyond. We are interested in feedback on how we could construct a cross-cutting measure requirement

that would be most meaningful to MIPS eligible clinicians from different specialties and that would have the greatest impact on improving the health of populations (pg. 426).

We are seeking additional comments in this final rule with comment period from the public for future notice-and-comment rulemaking on approaches to implementation of cross-cutting measures in future years of the MIPS program that could achieve these program goals and be meaningful to MIPS eligible clinicians and the patients they serve (pg. 613).

Topped-Out Measures – We seek comment on whether, for the second year a measure is topped out, to use a mid-cluster scoring approach, flat rate percentage approach or to remove topped out measures at this time (pg. 1077) We seek comment on how topped out measures would be scored provided that it is the second year the measure has been identified as topped out (pg. 1083).

We seek comment on whether we should remove non-outcomes measures for which performance cannot reliably be scored against a benchmark (for example, measures that do not have 20 reporters with 20 cases that meet the data completeness standard) for 3 years in a row (pg. 1090).

EHRA Response

Regarding the indication in the final rule to “monitor whether clinicians appear to be switching measures to improve their scores, rather than due to changing medical goals or patient populations,” the EHRA is concerned about the method for monitoring that would take place and the possible consequences for clinicians that switch measures. It is in clinicians’ best interests to use the measures that represent their best work and the abundance of options CMS allows in the measure selection would promote this as well.

EHRA would like to express appreciation and support of the flexibility CMS has allowed clinicians in the quality category.

Third Party Intermediaries

We are finalizing requirements for third party data submission to MIPS that are intended to decrease burden to individual clinicians. Specifically, qualified registries, QCDRs, health IT vendors, and CMS-approved survey vendors will have the ability to act as intermediaries on behalf of MIPS eligible clinicians and groups for submission of data to CMS across the quality, improvement activities, and advancing care information performance categories (pg. 37).

EHRA Response

The EHR Association appreciates CMS’ efforts to incorporate the use of health IT in transforming the way eligible clinicians deliver care via improvement activities (IAs), as well as the ability for ECs to earn bonus ACI points by demonstrating use of CEHRT in IAs. We remind CMS and eligible clinicians that EHRs are not certified to report IAs electronically beyond attestation and thus look to CMS to provide timely guidance on how the yes/no information for completed activities should be submitted electronically via the attestation method. If EHR developers have to add a tool to track the yes/no attestation for the 90+ activities, EHRA believes that work adds little value to providers and is not the best use of EHR technology.

Advancing Care Information

We are seeking comment on this integration of the improvement activities with the advancing care information performance category, and other ways to further the advancement of health IT measurement (pg. 788).

We are seeking comment in this final rule with comment period on what would be an appropriate threshold for group reporting in future years (pg. 813).

We would also welcome concrete proposals for new measures as we move forward with EHR reporting requirements under the MIPS. We are eager to improve interoperability and would welcome suggestions for improvement (pg. 821).

We are seeking comment on our final scoring methodology policies, and future enhancements to the methodology (pg. 849).

We note that we will consider new measures for future years of the program, and invite comment on what types of EHR measures and measurement should be considered for inclusion in the program. In addition, we invite comments on how to make the measures that we are adopting in this final rule more stringent in the future, especially in light of the statutory requirements (pg. 893).

EHRA Response

CMS requests comment on several aspects of the advancing care information category:

- **Integration of Improvement Activities**

We support CMS's assessment that using certified EHR technology can aid in improving clinical practices and help healthcare organizations achieve success on numerous improvement activities.

- **Scoring Methodology Policies**

CMS asks for comments on their scoring methodologies and areas for future enhancement. The differences in scoring methodology between Medicare and Medicaid reporting cause complexity and waste for ECs. An EC who is reporting on objectives for both MIPS and for his or her state's Medicaid meaningful use program needs to track two separate sets of requirements, monitor two different reports, and complete two different submissions. In future reporting years, we suggest that CMS provide Quality Payment Program (QPP) attestation data directly to state programs. CMS has already defined what a "meaningful user" is in the MIPS and Advanced Payment Model (APM) Final Rule. If a provider successfully attests as a meaningful user to CMS for the Medicare Quality Payment Program, CMS should provide that data to the provider's state so that the provider also counts as a meaningful user for his state's Medicaid program. By counting Medicare submissions for state programs, CMS can streamline and simplify the reporting process so that providers have a single set of requirements to track and a single submission.

CMS states that the concerns about low thresholds are addressed by requiring only a one in the numerator and denominator for ACI measures (pg. 77237). However, in some cases, specialists

will not have a one in the denominator because the measure is outside of their scope of practice. To accommodate these specialists and to allow them to report successfully in the ACI category, CMS should change the denominator threshold to zero for all measures required to be reported as part of the base score. Alternatively, CMS could create an exclusion or another method to exempt eligible clinicians from measures in the base score that are beyond their scope of practice.

Submission Methods

We are seeking comment on whether we should modify this policy to allow combined scoring on all measures submitted across multiple submission mechanisms within a performance category.

Specifically, we are seeking comment on the following questions (pg. 1042):

- *Would offering a combined performance category score across submissions mechanisms encourage electronic reporting and the development of more measures that effectively use highly reliable, accurate clinical data routinely captured by CEHRT in the normal course of delivering safe and effective care? If so, are there particular approaches to the performance category score combination that would provide more encouragement than others?*
- *What approach should be used to combine the scores for quality measures from multiple submission mechanisms into a single aggregate score for the quality performance category? For example, should CMS offer a weighted average score on quality measures submitted through two or more different mechanisms? Or take the highest scores for any submitted measure regardless of how the measure is submitted?*
- *What steps should CMS and ONC consider taking to increase clinician and consumer confidence in the reliability of the technology used to extract, aggregate, and submit electronic quality measurement data to CMS?*
- *What enhancements to submission mechanisms or scoring methodologies for future years might reinforce incentives to encourage electronic reporting and improve reliability and comparability of CQMs reported by different electronic mechanisms?*

EHRA Response

CMS's intent to "encourage electronic reporting and the development of more measures that effectively use highly reliable, accurate clinical data routinely captured by CEHRT in the normal course of delivering safe and effective care" (pg. 77275) will make good use of health IT tools in use by providers. As providers take advantage of these tools, CMS should consider retiring non-electronic reporting mechanisms. Focusing on electronic submission will permit CMS and health IT developers to invest more time in facilitating the ease of the electronic process rather than having to split their time to meet the many options for submission.

CMS can also increase provider confidence by providing immediate feedback about measure calculation. If CMS provides real-time feedback, providers could make adjustments throughout the reporting period to improve performance and validate calculation, while minimizing the risk of unexpected results at the end of the reporting period.

CMS will also want to streamline the submission process by continuing to use national standards for quality data submission that can also be used by other quality receivers, such as states and private

payers. Conversely, if CMS adopts a proprietary format, it would divert attention from national work on interoperability and hinder alignment.

Stratify by Size:

However, we continue to receive feedback that small practices should have a different benchmark, so we seek comment on any rationales for or against stratifying by practice size we may not have considered (pg. 1068).

EHRA Response

- **MIPS Scoring**

As described in the Final Rule, MIPS scoring is designed to change over time, and CMS asks for comment on how to establish benchmarks in future years. For future benchmarks to be effective, they must be transparent and predictable. Benchmarks need to be published far enough before the start of the reporting period so that providers can monitor their performance and gauge their score throughout the year and understand the thresholds they are trying to achieve.

- **Quality Category**

CMS has designed the quality category so that performance will be determined based on benchmarks for each measure. However, as of December 2016, these benchmarks are not yet available. Clinicians will begin reporting on MIPS in 2017 but do not yet have benchmarks to gauge their performance or to set a goal. This presents a challenge as clinicians attempt to use reporting tools to track their progress on quality measures and do not know the benchmarks that they are trying to achieve. For clinicians to successfully track performance and improvement throughout the 2017 reporting year, CMS needs to release benchmarks as soon as possible so that clinicians can integrate them into their reporting tools and processes.

In addition to the responses above to your questions, we would like to submit the following comments for your consideration in future rulemaking:

- **Reporting Formats** (pg. 77372)

We suggest that CMS continue to establish data transmission formats for quality measures in conformance with the 21st Century CURES bill, which give deference to accepted industry standards published by standards development organizations.

- **Health Information Exchange (HIE) as an Advanced APM CEHRT Requirement** (pg. 77414)

We request clarification that “participation in an organization facilitating HIE into the Advanced APM CEHRT requirement” does not necessarily require an actual HIE organization, but can be achieved by other means of health information exchange. The essential objective seems to be that, with an advanced APM, there is commitment among the participants to actively exchange information. This can be achieved through a variety of means, any of which should be considered appropriate. Health information exchange could be achieved using Direct exchange, through networks and frameworks such as Commonwell, Carequality, or eHealth Exchange, through state or private HIE organizations, or any combination of these.

- **Information Blocking Attestation** (pg. 77030)

We support CMS’ intent to discourage information blocking, which is also reflected in the [EHR Developer Code of Conduct](#) that all EHR developers are encouraged to adopt:

“We will enable, to the greatest extent possible, our clients to exchange clinical information with other parties involved in the care of a patient, including those using other EHR systems, through standards-based technology. Given our strong support for interoperability, adherents to the Code do not engage in data blocking.”

As the industry gains more experience with the nuances involved with evaluating possible information blocking in what are likely to be many situations that lie between those examples that are clearly blocking and those that are not, we request that CMS and ONC be transparent in their findings so that we may all improve our understanding of what is and what is not considered information blocking. This approach should include de-identified examples where a concern of information blocking was raised but found not to be taking place as well as instances where information blocking is found to be occurring.

We suggest further clarification regarding the definition of “structured” in the phrase “trusted bi-directional exchange of structured electronic health information.” While exchanging just PDF files is not desirable, receiving PDF files is better than receiving nothing at all. At the same time, rather than sending PDFs, we want to promote the use of standards and implementation guides that support structured data to the greatest extent practical to enable downstream use beyond viewing (e.g., outcomes analysis, clinical decision support).

We also find that the recently passed 21st Century CURES bill does not include the notion of “structured” in its definition of information blocking. We recommend that this definition be put into operation by considering the availability of standards and implementation guides that describe the extent of structured required based on industry consensus of what is appropriate and necessary. For example, when data is exchanged using industry accepted standards and implementation guides (e.g., those recognized in ONC’s certification edition), it should be considered “structured” even though certain content may be unstructured free text. Where standards are not recognized and/or available, we should recognize that sending information may occur at various levels of (un-)structure. This should not be considered information blocking per se when the data is not fully structured but is still being exchanged. We appreciate that removing the word “structured” may not be feasible at this time, but request that sub-regulatory guidance clarify this distinction.