

33 W. Monroe, Suite 1700 Chicago, IL 60603 <u>swillis@himss.org</u> Phone: 312-915-9518 Twitter: @EHRAssociation

AdvancedMD

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June 27, 2016

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-5517-P P.O. Box 8016 Baltimore. MD 21244-8016

On behalf of the Electronic Health Record (EHR) Association, we submit the following comments on the Centers for Medicare and Medicaid Services Notice of Proposed Rulemaking (NPRM) on the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models. These comments are based on the collective perspectives and experiences of more than 30 Association member companies who serve the majority of hospitals and ambulatory care providers using EHRs across the US.

The EHR Association recognizes the complexity of the MACRA legislation, and appreciates CMS considering a variety of comments, suggestions, and input from a diverse set of stakeholders in developing the proposed rule. We commend CMS' attempts to streamline and simplify existing quality, payment, and incentive programs. Our feedback offers recommendations to ensure this transition is as successful as possible while meeting the Secretary's goals for delivery system reform and the intended implementation of the statute.

We must emphasize that the complexities of the Quality Payment Program (QPP) as outlined in the proposed rule will lead to many significant changes and implications for eligible clinicians (ECs), many of which will take effect in less than 12 months. Based on our broad initial stakeholder assessment of the proposed rule, we urge CMS to take every possible step to dramatically simplify provisions and requirements, and to revise and develop provider-focused communications to reduce remaining perceived complexity.

Given our unique relationship with providers, we offer our assistance in working with CMS and others to increase awareness among clinicians and provide education to help them prepare for implementation in 2017. Although this is a proposed rule, we urge CMS to act immediately on the premise that implementation for 2017 should begin now with clear education and guidance from the agency in order to ensure successful transitions to the new QPP.

Our key recommendations include:

Advanced Payment Models (APMs)

- To ensure the success of new payment models, we recommend that CMS engage the health IT community before introducing additional new APM models that rely heavily upon our products and services, especially if those models have unique or specialized technology requirements, whether explicitly identified or simply implied.
- We believe that CPC+ models should be eligible for Advanced APM status for the full five years of the demonstration. We, therefore, encourage CMS to revisit the 50-clinician maximum for the alternative patient centered medical home (PCMH) model risk criteria, as applying this limit to the parent entity sponsoring the PCMH, rather than the PCMH itself, seems to unduly limit the application of the alternative risk approach and could deter participation in new medical home models.
- Additionally, we urge CMS to adopt a model that allows ECs to be promptly notified whether or not they will qualify for Advanced APM payment in a given performance year, and therefore do not need to participate in MIPS for that year.

Surveillance and Information Blocking Attestations

- With regard to the first part of the three-part data blocking attestation, we request and expect
 regulatory guidance with additional clarity on what the attestation means; if there are
 extenuating circumstances that would serve as exceptions; and, how a provider would
 substantiate that they had acted in accordance with the attestation.
- We believe the second and third data blocking attestations go beyond what Congress intended or authorized in MACRA and suggest that they are not necessary and should not be retained in the final rule.

Clinical Practice Improvement Activities (CPIA)

- We recommend that CMS enhance the clarity of the CPIA definitions in the final rule and subregulatory guidance so that providers can know what they must do to qualify for a given CPIA. Further, we request explicit clarification that EHRs are not required to capture or report any metrics for CPIA that fall outside of the requirements for 2015 EHR certification.
- We request clarification on how providers will attest to CPIA.

Quality Reporting

- CMS should provide a minimum of 18 months' notice for newly developed quality measures and benchmarks preceding the reporting period for which they are required. The first 12 months will allow for vendor implementation, with another six months allocated for real-world beta testing of measures as well as identifying and resolving defects and inconsistencies in a measure update for implementation the following year. We request a minimum of six months' notice prior to any reporting period for implementation of revised measures.
- We urge CMS to allow quality measures to be reported by a provider and accepted by CMS using multiple reporting methods.
- We urge CMS to increase measure e-specification on a priority basis and encourage the creation of more specialty measure sets over time to continue to build upon those already proposed.
- The Association recommends separate timelines for new measures as opposed to updated specifications. We request that when changes to the list of MIPS quality measures are made, those changes are not expected to be implemented until at least 18 months after they are announced.
- We suggest that CMS remove the one-point cap for the public health reporting bonus and award additional points for multiple types of submissions.

Advancing Care Information (ACI)

- The Association recommends the inclusion of computer-based provider order entry (CPOE) and eRx in the performance score to give providers more flexibility, especially for ECs participating in MIPS using 2014 Edition certified technology in 2017.
- Regarding performance scoring, we ask CMS to confirm that providers who transition from 2014 Edition CEHRT to 2015 Edition CEHRT during the 2017 year may use either the modified Stage 2 ACI measures or Stage 3 ACI measures.

Third Party Submission

- Regarding third party submission, the EHR Association proposes that at least 30 days be allowed for the corrective action plan and an additional 45 days to deploy the solution. In addition, the imminence of a reporting deadline should not limit the time available to deploy a solution; such haste could create additional problems for providers and CMS. Moreover, CMS should have provisions in place to use updated data submitted after the reporting deadline.
- It will be important not to penalize submitters with errors in calculations in excess of the three to five percent in the proposed rule if the calculation error is due to a different interpretation of an imprecisely-specified measure.
- Beyond what is already required for CEHRT certification, we do not believe that CMS should force third party intermediaries to implement reporting capabilities that may be outside of their organizational and client priorities.

We look forward to working with CMS and other stakeholders to ensure that these important efforts to move to a value-based healthcare system are well supported by EHRs and other health IT.

Sincerely,

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Leigh Burchell Chair, EHR Association Allscripts

gaup O. Cally MB, FACP

Sarah Corley, MD Vice Chair, EHR Association NextGen Healthcare

HIMSS EHR Association Executive Committee

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Pamela Chapman e-MDs

Meg Marshall, JD Cerner Corporation

Suland My min MD

Richard Loomis, MD Practice Fusion

Rick Reeves, RPh Evident

Dickard Landen

Richard Landen QuadraMed Corporation

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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 <u>www.ehrassociation.org</u>.

Electronic Health Record Association Comments on the Centers for Medicare and Medicaid Services Notice of Proposed Rulemaking (NPRM) on the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Advanced Payment Models (APMs)

APM CEHRT

The Association supports CMS' decision to maintain the same EHR certification requirements across the MIPS and APM programs. We support keeping the technology requirements aligned for all the reasons noted in the proposed rule and urge CMS to maintain this approach in later years. In particular, we see that many ECs will be interested in transitioning from the MIPS track into various APMs over the coming years. Keeping the EHR certification requirements consistent between those tracks ensures that ECs are not faced with an unnecessary challenge of needing different or additional technology prior to APM participation, especially as Advanced APM status will not be known at the start of the 2017, and likely future reporting years, as CMS acknowledges. Moreover, we expect to see a variety of innovative APM constructs and the associated technology needs to support their workflows. Defining different certification requirements for Advanced APMs, especially with the expected diversity in such organizations, will stifle the market's ability to innovate and provide creative technology solutions for APM participants.

The EHR Association also supports CMS' simple approach to allowing APM entities to indicate that Certified EHR Technology (CEHRT) is being used by ECs for the indicated functions.

Process for Introducing New APMs

Health IT is and will continue to be an integral component of alternative payment models, providing much of the data collection, reporting, and analytic capabilities providers must leverage to successfully participate in APMs. Our members are pleased to play such a key role in efforts to reform our healthcare delivery system and incentivize value over volume. We appreciate that CMS seeks to encourage innovation in the development of new APMs, particularly Advanced APMs.

To ensure the success of new payment models, we recommend that CMS engage the health IT community before introducing additional new APM models that rely heavily upon our products and services, especially if those models have unique or specialized technology requirements, whether formally listed or simply implied. Doing so will allow us to commit with confidence that we can support providers in meeting the requirements of the APM, and, more broadly, the intent of the MACRA legislation.

We support the proposed plan to announce the Advanced APM status of a new payment model in conjunction with the first public notice of the model. Such Advanced APM determination is a critical piece of information that ECs will need when making participation decisions. However, we disagree with the proposal to revoke the Advanced APM eligibility of the CPC+ payment model for participants with more than 50 clinicians in their parent organization in 2018, based on proposed post-2017 changes in eligibility for the alternative patient-centered medical home (PCMH) model risk criteria. We believe that CPC+ models should be eligible for Advanced APM status for the full five years of the demonstration.

We, therefore, encourage CMS to revisit the 50-clinician maximum for the alternative PCMH model risk criteria, as applying this limit to the parent entity sponsoring the PCMH, rather than the PCMH itself, seems to unduly limit the application of the alternative risk approach and could deter participation in new medical home models.

Additionally, we urge CMS to adopt a model that allows ECs to be notified promptly whether or not they will qualify for Advanced APM payment in a given performance year, and therefore do not need to participate in MIPS for that year. We anticipate that ECs will see avoiding the burden of MIPS reporting as a key incentive for Advanced APM participation. However, if they are forced to report for MIPS to mitigate the risk that they will not be designated as qualifying participants in Advanced APMs in any given year, then that incentive is negated. Fundamentally, lack of certainty around qualifying for Advanced APM participation in new payment models so clarity is crucial for success.

Merit-based Incentive Payment System (MIPS)

Timeframe

We are pleased with the new and more flexible reporting requirements, which streamline multiple quality reporting programs into a single system. However, given that these regulations will not be finalized until the fall of 2016, it will be very challenging for physicians and vendors to get ready for the first performance year of 2017, especially with the major changes proposed in ACI structure and reporting methods and levels (e.g., group, TIN/NPI). Recognizing that many quality measures are designed around full year reporting, that Resource Use does not require EC submission, and that CPIAs are already proposed for 90-day performance, we ask that ACI reporting be for any consecutive 90-day reporting in 2017.

Surveillance and Information Blocking Attestations

On behalf of our provider clients, we have significant concerns with the proposed attestations regarding surveillance and information blocking under the MACRA/MIPS program.

First, with respect to ONC or ONC-ACB surveillance, we are concerned that the proposal will impose significant costs and uncertainty on providers. In addition, the proposed rule indicates that as part of in-the-field surveillance, ONC and/or ACBs can review data stored in CEHRT. We seek clarification that the scope of this surveillance includes only data maintained to support certified capabilities, not any other capabilities that may be part of the software solution that includes CEHRT.

Second, we believe that the data blocking and interoperability attestations go beyond the requirements of MACRA and what should be expected via provider attestation. We do want to emphasize the very strong support of the Association for interoperability and opposition to true data blocking. We do not think that this proposal is the appropriate approach to advance these priorities and that it will impose costs that far exceed any benefits.

In the first part of the three-part data blocking attestation, the NPRM proposes to require, per the MACRA statutory requirement, that "an EP must demonstrate that he or she has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology." This is appropriately matched to the legislative intent,

though we request and expect regulatory guidance with additional clarity on what the attestation means; if there are extenuating circumstances that would serve as exceptions; and how a provider would substantiate that they had acted in accordance with the attestation. Certainly, some entirely reasonable activities could be construed as problematic given this attestation language. For example, if an office-based clinic periodically turns their computer network off overnight to perform computer maintenance when they are closed, has that "limited" interoperability for other provider organizations that might attempt to request records during that time?

The second and third attestations in this section go beyond what Congress intended or required in MACRA and will impose wasteful uncertainty and significant risk on providers. We also point out that these two statements appear to imply CEHRT capabilities that are not in the current 2015 Certification Edition. They are not necessary and should not be retained in the final rule. Instead, the way to encourage and ensure greater interoperability is through broad-scale changes in payment and incentive models, as otherwise exemplified by this proposed rule.

More specifically, we emphasize that the second statement is virtually incomprehensible in its multiple provisions and, as indicated, appears to be limited to the capabilities defined in the 2015 Certification Edition, particularly when the issue is connection with unaffiliated providers.

• For example, use of the Direct standard can support certain interoperability capabilities through the standards adopted in the 2015 Certification Edition. However, there is widespread use of health information exchanges (HIEs) and network-to-network exchanges that do not necessarily use standards or approaches referenced in the 2015 Certification Edition or implied by the attestation. Exchange through other methods than those explicitly included in CEHRT should not be excluded from consideration and should not lead to concluding that information blocking is in play. Moreover, Direct is problematic for many potential adopters, and low use of Direct is not in itself indicative of potential information blocking, particularly when there is substantial sharing of information occurring through HIEs and network-to-network exchanges that are not Direct-based. We suggest that this issue should be revised and clarified if this attestation is retained.

In addition, the third statement requires a broad and general attestation that the provider responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information. We suggest, if this attestation is retained, which we oppose, that it be revised to apply only to requests made in accordance with the standards and capabilities in the 2015 Certification Edition (or 2014 prior to 2018). More generally, aside from technical issues, we believe that the broad requirements in this attestation will create significant uncertainty among providers, with the same challenges in proving compliance and dealing with understandable exceptions that apply to the first and second attestations.

• For example, queries initiated through a Direct message cannot consistently be responded to electronically, if at all, as there are no widely-adopted standards on how to convey the query or the response within such a Direct message. Thus, a request made for data retrieval using Direct messages with embedded queries should be allowed to be declined, as insufficient standards exist; while requests to use mechanisms for which retrieval standards/mechanisms have been included (e.g., APIs) should be addressed in good faith and in a timely manner.

Clinical Practice Improvement Activities (CPIAs)

Overall, we believe that this category has the potential to enable Quality Payment Program (QPP) requirements that are more relevant to the needs and circumstances of particular specialties and clinicians, and enhance the focus on outcomes. At the same time, we see important opportunities for clarity and simplification.

Generally, our concern is that, given short and ambiguous definitions in Table H, providers will attest to activities in their MIPS submission, or needlessly avoid a given CPIA, based on varied understandings of what satisfying the activity entails. We recommend that CMS enhance the clarity of the CPIA definitions in the final rule and provide sub-regulatory guidance so that providers can know what they must do to qualify for a given CPIA. This clarity should include:

- 1. Where a general and non-specific definition is intentional to permit providers flexibility, and also how they expect ECs to meet and substantiate such a CPIA requirement.
- 2. Specifying the evidence that providers would be expected to retain as documentation and to provide an auditor.

Prior CMS sub-regulatory guidance on audit documentation for non-percentage-based measures provides a useful example.

We are concerned that some activities in Table H imply specific percentage-based measurements that ECs may expect to be tracked in an EHR, but for which the EHR has not been designed to do so; and the costs of adding such functionality are not offset by sufficient benefits. For example, in the population management category (Table H, p. 947), an activity pertaining to patients on anticoagulation medications has the following "requirements:"

- MIPS-eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, in the first performance year, 60 percent or more of their ambulatory care patients receiving warfarin are being managed by one or more of these clinical practice improvement activities:
 - Patients are being managed by an anticoagulant management service that involves systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions;
 - Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions;
 - For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or,
 - For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.

• The performance threshold will increase to 75 percent for the second performance year and onward. Clinicians would attest that 60 percent for first year, or 75 percent for the second year, of their ambulatory care patients receiving warfarin participated in an anticoagulation management program for at least 90 days during the performance period.

It is unrealistic to expect that an EHR would be able to validate that each anticoagulation management program meets all of the criteria specified above, or that reports could be generated demonstrating that 60-75 percent of warfarin patients were managed in such a way. Use of the term "validated" to describe the electronic clinical decision support implies that there is a source for that validation which is not specified.

There are measures that are similar but differ in whether they are high value or medium value, such as QCDR measures. Examples and further clarity as to the characteristics that would be necessary to attest to the higher value activity will reduce the risk of confusion, particularly by auditors.

Because it is generally accepted in quality improvement circles that no more than three projects should be tackled at once to increase focus on achieving success and sustainability, consideration should be given to grouping related activities that logically might be considered to be components of a single quality improvement project, but still count towards the total of six items required by the bulk of the measures which are only valued at 10 points. Alternatively, counting all activities as high value activities worth 20 points would reduce complexity and ambiguity, and allow practices to truly focus on improving measures where their performance would benefit from a targeted intervention. Again, using QCDRs as an example, it should be clarified that a single QCDR can be counted for multiple instances if it supports many of the separately identified components in the proposed rule.

Please provide specificity regarding how it is expected that providers will attest to these activities. Will there be a list of all 90 activities mentioned in the rule, and they are to attest yes/no to each? If vendors are expected to add the ability to collect attestations on these activities and report them, software development will be required, especially if it is proposed that all 90 be included as is suggested by the sample QRDA-III HTML provided.

More generally, beyond percentage-based CPIAs, because providers will need to be able to substantiate their CPIA attestations if they are audited, it needs to be made clear to ECs and auditors that EHRs need not be the source of validation that the CPIA criteria have been met. Creating the means to track activities via measurements that are not a byproduct of provider workflow will create usability problems, divert development resources from other provider priorities, and unduly complicate clinical workflows.

Quality Reporting

The EHR Association strongly supports the CMS goals of patient-centered health care, and the aim of the MIPS program for evidence-based and outcome-driven quality performance reporting. We appreciate that the flexibility allowed in the MIPS program, including the variety of reporting options, is intended to meet the needs of the wide variety of eligible clinicians. The variety of reporting options, however, can easily create confusion due to the increased number of choices and methods. Such confusion will be challenging in general, but could be especially problematic for 2017, given the short time to prepare.

We also note that although Congress did mandate an evolution in category weights in initial program years, the annual changes in category percentage changes will reduce program continuity and change MIPS score calculations each year. This annual shift in the formula for calculating the Composite Performance Score (CPS) will make it more difficult for a clinician to determine goals as they transition to subsequent reporting periods. As health IT vendors, our member companies have a great deal of experience in being part of the support system for clinicians to help them understand the complexities of quality programs. We recommend clear, well-defined, and detailed guidance on the options so that all parties involved in the support of clinicians participating in the program can assist in making the program a success.

We support the proposed removal of the constraint on NQS domains and the reduction to six measures for reporting as a move toward greater flexibility in the quality category. We also support the proposed bonus points for the use of certified EHR technology, as this is foundational to the functionality needed for a quality program of this magnitude.

EHRA member companies invest a great deal of resources in development and implementation of quality measures, and support and encourage development of processes that result in the best possible quality measures. Well-vetted measures developed with multi-stakeholder involvement lead to measures that are better designed to be useful for longer periods of time in the field.

We recommend reconsideration of the requirement that all quality measures that are used by CMS must come from the same reporting method. In particular, we urge CMS to allow quality measures to be reported by a provider and accepted by CMS using multiple reporting methods. As CMS itself reflects in the NPRM preamble, there are appropriate avenues of reporting, depending upon different types of measures. For example, a patient experience measure may be very difficult to submit via EHR methods because the patient survey data is not captured in the clinician's EHR. In addition, several specialty measure groupings have very few (cardiology, orthopedic surgery) or no (e.g., general surgery) EHR submission-eligible measures, but ECs should be able to use EHR submission where available.

The specialty-specific measure sets are a welcome addition, as EHR Association members have worked with many clinicians requesting this flexibility. We also support the proposals calling for additional electronic measures, and encourage the creation of more specialty measure sets over time to continue to build upon those already proposed. As the specialty sets stand now, there are many with fewer than six measures, and even fewer that include an outcome-based measure. In addition, as indicated, many of the specialty sets have very few or no EHR submission-eligible measures. We urge CMS to increase measure e-specification on a priority basis.

It is unclear whether the annual measure updates require recertification of modified existing measures. We suggest that they should not, consistent with the approach in the meaningful use program's handling of updates to existing CQMs. If re-certification is expected, this would be another reason for more time to be provided between the release of an updated specification and the expected implementation. This timetable should be clearly outlined so that providers may gain a clear understanding of this concept. Any changes to quality measures should be done with at least six months of lead time to allow for coding, testing, and rollout of the updated measure. If significant changes are made to the data that is to be collected for a measure, it should be treated as a new measure with an 18-month time period between release and expected use.

Introducing New Measures and Timelines

The current process for annual measure updates, and the proposed November 1st deadline for quality measure updates for the next reporting year, is not consistent with health IT implementation timelines. With the number of measures anticipated to grow dramatically, receiving the annual list of quality measures for MIPS by November 1st of the year prior to the first day of the performance period does not provide adequate time to analyze, develop, test, and implement a measure. Should measures require that new fields or functionality be added to support them, then even more lead time is necessary to allow for clinician testing, training, upgrading, and incorporation into workflows which must occur before the start of the reporting period.

The Association recommends separate timelines for new measures as opposed to updated specifications. Based on industry experience with the lack of maturity of new CQMs introduced to the meaningful use program, we suggest that for the first year a measure is introduced it should be pilot tested so that the details and components of the measure can be evaluated as to how it is used and performs. We have consistently requested 18 months between the announcement of a change in required functionality and the expected implementation date. We request that when changes to the list of MIPS quality measures are made, those changes are not expected to be implemented until at least 18 months after they are announced. If there is a pressing public health need to roll out a new measure earlier, or if a vendor wishes to provide that measure to its clients earlier than 18 months later, ECs should be able to report on a measure that was certified prior to the submission deadline and not prior to the start of the reporting period.

Quality Measure Benchmarks

The procedure s to benchmark provider performance must be tested, transparent, and trusted by physicians. The process should include multi-stakeholder input and be clearly communicated. We caution against calculating a benchmark during the early stages of MIPS which will be a period of uncertainty.

The rule proposes that all MIPS-eligible clinicians, regardless of whether they report as an individual or group, and regardless of specialty, submit data using the same submission mechanism and would be included in the same benchmark. Physicians should only be compared to similar physicians with similar patient populations in similar settings.

Advancing Care Information

Overall, we appreciate and support CMS' efforts to simplify the current meaningful use program as it designed the new Advancing Care Information (ACI) provision. The effort to reduce all-or-nothing scoring and to focus performance measurement on data exchange and interoperability are responsive to industry priorities and stakeholder feedback. As detailed below, we do see continuing opportunities for simplification and revision. Also, for simplicity, we ask that CMS consider applying final ACI approaches to Medicaid eligible professionals and for hospitals under the meaningful use program.

Base Score

First, we generally support the proposed one-patient denominator/numerator as an effective measure for the ACI base. Counting one patient in a denominator and numerator is practical given current capabilities of 2014 Edition certified EHRs, and serves as a reasonable proxy that EHRs are implemented and used.

However, we urge CMS to revisit the issue of eliminating exclusions for base items given its all-ornothing approach and use for such a large portion of the total ACI score. Some providers who have been successful with meaningful use in the past might find themselves unable to achieve any ACI points if they have no patients in the denominator of any one base measure. In particular, the measure to send a summary of care document at transitions of care seems most problematic. Specialists often have no transitions in their denominator, and might end up ineligible for any base score or ACI points.

The Association discussed whether the structure of the base score puts sufficient emphasis on our national interoperability goals, which are also a goals strongly supported by the EHR Association. We believe that the base measure for HIE is a reasonable proxy to ensure interoperability features are adopted, while further use of those features would be prioritized by the performance score.

Measuring public health reporting with a primary focus on submission of immunizations to public health registries is reasonable. Immunization registries are the most widely available and applicable public health registries and previously included for EPs in meaningful use. The continuation of the exclusions for providers who do not administer immunizations, or whose local registries do not accept data according to the standards adopted in certification, ensures that providers are not penalized for factors beyond their control.

Public Health Bonus Point

Scoring only one additional point for other public health submissions seems to minimize their importance. We suggest that CMS consider not capping the bonus point at one, but award additional points for multiple types of submission. If a provider has already invested in public health reporting for syndromic surveillance, cancer case reporting, and clinical data registries, then this approach more equitably rewards their efforts.

Performance Scoring: Topped Out Measures

CMS has previously retired meaningful use measures that they have defined as "topped out" due to historically receiving very high scores. We suggest that the patient education measure be considered "topped out," due to historically high performance. In addition, we have repeatedly expressed concern that the manner in which the patient education measure is currently specified is overly constrained and limiting to providers who may prefer workflows to provide patient education beyond what is permitted by CMS and certification.

The Association recommends the inclusion of CPOE and eRx in the performance score to give providers more flexibility, especially for ECs participating in MIPS using 2014 Edition certified technology in 2017. Demonstrating success with adoption of key EHR features around ordering for safety and efficiency, and for interoperable transmission of prescriptions, should be rewarded by the ACI scoring system.

Performance Scoring: 2017 and 2014 Edition CEHRT versus 2015 Edition CEHRT

Many providers will begin the 2017 reporting year using 2014 Edition CEHRT, and we would like clarification regarding their MIPS participation. The discussion in the Preamble of Performance Scoring was ambiguous regarding those who are still in Stage 2. First, we ask CMS to confirm that providers who transition from 2014 Edition CEHRT to 2015 Edition CEHRT during the 2017 year can report using either the modified Stage 2 ACI measures or Stage 3 ACI measures. Second, if ECs elect to use Stage 3 ACI measures, are they scored over the entire year, or only the time during which they used 2015 Edition CEHRT? For example, if a provider switches from 2014 Edition CEHRT to 2015 Edition CEHRT to 2015 Edition CEHRT in October,

would the Stage 3 scores for measures that are only supported by the new functionality be based on January to December or October to December? The implications for performance scores in this situation are significant. A 100 percent performance rate in the three months where the provider was able to meet the measure would translate to only a 2.5 percent performance rate when looked at over the course of the year.

There are different numbers of measures available for those still in Stage 2 in 2017 (six measures) versus Stage 3 (eight measures). Overall, the discussion of how those still in Stage 2 in 2017 would report and be scored for performance should be clearer. We urge that CMS take steps, including adding measures (see our above suggestion) or revising the scoring per measure for those in Stage 2, to ensure that those still in Stage 2 in 2017 are not unintentionally or unduly disadvantaged by only having access to six Stage 2 measures rather than eight Stage 3 measures.

Consistency

The changes suggested as part of MIPS create complexity because they differ from requirements for meaningful use still followed by EHs, CAHs, Medicaid EPs, and Medicare Advantage participants. CMS' proposal that providers will not be allowed to reuse Medicaid meaningful use reporting to meet MIPS ACI obligations, but will have to report twice, is especially burdensome. This situation will likely discourage participation in the remaining years of the Medicaid incentives, and could have the unintended consequence of reducing participation in Medicaid. Consideration should be given to allowing successful Medicaid attestation to count for 30 points in the ACI portion through the end of the incentive period in 2021.

Group ACI

CMS proposes a new method of reporting for ACI for groups not previously part of meaningful use. CMS has not provided any measure specifications for group reporting. To consistently implement group reporting across all EHRs, report logic will require clear specifications and time for development and distribution of report updates.

The specifications would need to be reviewed on a measure-by-measure basis to address data aggregation at the group level. For example, if two providers in the same group see the same patient, and one of the providers gives timely electronic access to the patient's information and the other provider does not, is the patient counted in the numerator? If the same provider saw the patient twice and only offered timely access once, CMS has previously indicated that would be insufficient to put the patient in the numerator. Will a similar policy be followed for groups?

For 2017 and 2018, we suggest that the only practical method to implement group reporting would be to sum the denominators and numerators of all group participants for submission. For example, if a group consisted of Dr. A, Dr. B, and Dr. C, and each of them had a score of 8/10 on a measure, then the group score would be 24/30, without regard for any potential overlap of unique patients seen.

Once CMS publishes specifications for group ACI reporting, we can provide additional feedback on the level of effort required for report revisions and a reasonable timeline for implementation.

Reporting by TIN/NPI

CMS proposes a new ACI reporting method for individuals, which was never previously part of meaningful use. Meaningful use was reported per NPI, and CMS proposes to report MIPS by TIN/NPI. Because providers work in an average of 1.2 TINs, this means that many providers will be affected.

Where a TIN division naturally matches an EHR division (e.g., a provider practices in two clinics, each is a different TIN, and each uses a different EHR), this approach will add convenience. However, where multiple TINs use the same EHR, rewriting ACI reports would be necessary to divide data by TIN, and to revise dashboards and other tools to help providers monitor the complexity of multiple metrics. Such report changes are not practical for 2017-2018 reporting years. For 2017 and 2018, providers practicing in multiple TINs using the same EHR should simply submit one ACI score (for the care provided across all TINs) for each TIN where they are participating in MIPS. Once CMS publishes specifications for TIN/NPI ACI reporting, we can provide additional feedback on the level of effort needed in report revisions and a reasonable timeline for implementation.

QRDA-Like Submission

CMS proposes a new method of reporting ACI electronically in a QRDA-like format. We appreciate CMS' recognition that, as this is a new format that is not yet specified, not all EHRs will support it in the earliest years of the program, and that alternate submission methods are also available. As the new format is defined, our members look forward to providing additional feedback on specifications, implementation guides, and testing tools.

Third Party Submission

CMS proposes a process for placing third party intermediaries (e.g., QCDR, health IT vendors, qualified registries, or CMS-approved survey vendors) on probation and for disqualifying such entities for failure to meet CMS standards. Specifically, CMS proposes that if it determines that an intermediary has not met all applicable requirements for qualification, CMS may place that intermediary on probation for the current performance period and/or the following performance period, as applicable.

CMS also proposes to require a corrective action plan (CAP) from the intermediary to address deficiencies or issues and prevent reoccurrence. CMS proposes that the CAP must be received and accepted by CMS within 14 days of CMS notification, and deficiencies corrected within 30 days or before the submission deadline. CMS also proposes that if the intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies affecting more than three percent (but less than five percent) of the MIPS ECs or groups submitted by the intermediary, CMS would publicize that the intermediary furnished data of "poor quality," and would place the entity on probation for the next performance period. Data errors affecting over five percent could lead to disqualification from the next performance year.

We appreciate the critical importance of accurate submitted data. We do believe, however, that the proposed error thresholds are too low (e.g., data audit discrepancies affecting in excess of three percent but less than five percent of the MIPS ECs or groups submitted). These thresholds as proposed do not take into account the materiality of the errors, or whether they are concentrated in specific providers, which could occur due to interactions between workflows and measure logic. There would also need to be exclusions for data calculation errors that could be attributed to poorly or inadequately specified measures. For example, a prior quality measure for a diabetic foot exam specified a code set for

exclusions that only included traumatic amputations and not the most common cause of amputation in a diabetic, a surgical amputation. Many vendors coded the logic to the intent of the measure which was to exclude patients who had no feet for any reason. A strict interpretation would find that to be an inaccurate calculation because it did not limit the logic to the identified codes. Until we have mature, well-vetted and error-free measures, this potential will continue to exist and should not result in probation or suspension.

In addition, 14 days could be much too little time to properly diagnose a problem and propose and test a solution. Similarly, 30 days could be much too little time to deploy a solution that could require patching software and changes in provider workflows. The Association proposes that at least 30 days is allowed for the CAP and an additional 45 days to deploy the solution. Also, the imminence of a reporting deadline should not limit the time available to deploy a solution; such haste could create additional problems for providers and CMS. CMS should have provisions in place to use updated data submitted after the reporting deadline.

CMS proposes that any third party intermediary must make available to CMS the contact information of each MIPS-eligible clinician or group on behalf of whom it submits data. The contact information will include, at a minimum, the MIPS-eligible clinician or group's practice phone number, address, and, if available, email. It is further proposed that the entity must retain all data submitted to CMS for MIPS for a minimum of 10 years. This seems like an unrealistic time period to require an intermediary to store data that has already been submitted to CMS.

Finally, CMS asks if in future rulemaking "... we should propose requiring health IT vendors, QCDRs, and qualified registries to have the capability to submit data for all MIPS performance categories." We believe that such a requirement for additional functionality or capability should not be imposed on any third party intermediary, especially as CMS has not deployed or evaluated its proposal to allow electronic submission of all applicable performance categories, notably ACIs and CPIAs. Beyond what is already required for CEHRT certification, we do not believe that CMS should force third party intermediaries to implement reporting capabilities that may be outside of their organizational and client priorities.

We ask for additional clarity regarding the requirement to "provide information on the entity's process for data validation for both individual MIPS-eligible clinicians and groups within a data validation plan." While it is reasonable to expect vendors who are also registries to perform quality assurance testing to confirm that calculations are correct and based on the data in the fields being samples, the language suggests a more detailed review of individual patients' charts, which would be impossible for vendors who are receiving only an extract of the fields necessary to calculate measures and not extracting the entire record.